Medical University of South Carolina
Protocol

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Study Title: **Care-coordination Approach to Learning Lupus Self-Management (CALLS)**

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A. SPECIFIC AIMS

List the broad, long-term objectives and the goal of the specific research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

Systemic Lupus Erythematosus (SLE or lupus) is a chronic autoimmune disease that is associated with high morbidity, mortality, and health care costs and decreased quality of life. In the United States, African Americans have three to four times greater prevalence of lupus, risk of developing lupus at an earlier age, and lupus-related disease activity, damage, and mortality compared with Caucasians, with the highest rates experienced by African American women. Persistent disparities may be due to the non-responsiveness of existing programs to the unique needs of African Americans and/or women with lupus and lack of sustainability. Peer mentoring interventions are effective in other chronic conditions that disproportionately affect minorities, such as diabetes, HIV, and kidney disease, but our Peer Approaches to Lupus Self-management (PALS) study was the first attempt to empirically test the peer mentoring approach in SLE patients. While preliminary data from our group suggest that peer mentoring improves self-management, reduces disease activity, and improves health related quality of life (HRQOL) in African American women with SLE, we have not demonstrated the long-term impact and cost-effectiveness of sustaining this approach in a medical setting. The Care Coordinator role has emerged in recent years as an important means of achieving significant outcomes for patients, their families, and the larger health system. These outcomes include increased patient satisfaction with service provision, an increase in patient access to services, and a decrease in the hospital length of stay and unplanned readmission. The most effective care coordination interventions are focused on providing holistic, relationship-based care. The success of relationship-centered peer mentoring has been attributed to the non-hierarchical, reciprocal relationship that is created by sharing similar experiences and the tendency of peer mentoring relationships to be consistent with the individual's social and cultural beliefs, making this the ideal interventional approach for a condition that disproportionately affects minority women. Mentoring from peers can establish trust and in turn decrease disparities in health care outcomes. Having a lay patient navigator on the healthcare team could sustain the benefits of a peer mentorship program designed to provide modeling and reinforcement by peers to encourage other patients with SLE to engage in activities that promote disease self-management. Having a plan for defining the role of the navigator/coordinator, targeting inpatient admissions to prevent readmissions as a marker of failed self-management, assessing cost effectiveness, and evaluating this service for program refinement, will facilitate an effective argument about sustainability.

To begin to fill this research void, the aims of this pilot will be three-fold:

AIM 1: Determine the feasibility of making a lay patient navigator/care coordinator available to SLE inpatient admissions.

AIM 2: Determine the impact of making a lay patient navigator/care coordinator available to SLE inpatient admissions on disease self-management, disease activity, HRQOL, and readmissions as a marker of failed self-management.

AIM 3: Collect resource use and cost information to plan a well-designed economic study of the cost-effectiveness of the use of lay-navigators for SLE patients in the acute care setting.

This study will provide preliminary evidence on the cost-effectiveness of a lay patient navigator/care coordinator for patients with SLE. The immediate goal of proposed work is to provide pilot data on cost savings, cost effectiveness, and patient outcomes to refine approaches, service components, and measures, for future grants. Once effectiveness of the program is demonstrated, the long-term goal is to disseminate this potentially cost-effective approach in diverse clinical and community settings. The objectives of the proposed pilot project are directly responsive to high priority areas of national funding agencies. For example, the Patient-Centered Outcomes Research Institute (PCORI) is interested in funding projects that focus on improving patient-centered and clinical outcomes. National Institutes that traditionally fund lupus-related research such as NIDDK and NIAMS also have research objectives that include reducing the human and economic burden of diseases that disproportionately affect minorities. Proposed work also responds to initiatives that focus on self-management to reduce the burden of chronic illness. Thus, relevant future funding opportunities include R01-level calls such as PA-14-344 “Self-Management for Health in Chronic Conditions (R01)” and PA-16-007 “Personalized Strategies to Manage Symptoms of Chronic Illness (R01)”; PA-14-290 “ARHQ Health Services Research Demonstration and Dissemination Grants (R18)”; and PCORI Funding Announcement: Addressing Disparities.

B. BACKGROUND AND SIGNIFICANCE

Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and health relevance of the research described in this protocol by relating the specific aims to the broad, long-term objectives. If the aims of the study are achieved, state how scientific knowledge or clinical practice will be advanced.

Significance

The proposed project is significant because it has the potential to provide a viable solution to address disparate adverse outcomes associated with Systemic Lupus Erythematosus (SLE). Our approach maximizes chances of success in improving disease self-management and quality of life, and decreasing indicators of disease activity among lupus patients by 1) Addressing the public health burden of SLE. SLE (or lupus) is a chronic autoimmune disease with acute periodic flare-ups of symptoms impacting any organ system and resulting in potentially life-threatening complications.[1-3] In the United States, the number of patients with lupus exceeds 250,000. Annual costs associated with SLE are estimated to be $10,000-$50,000 more than those for patients without SLE.[4-24] Major cost drivers include inpatient hospitalizations,[20,25,26] long disease duration, high disease activity and damage, poor physical and mental health, and low education and employment levels. Patients are also disproportionately impacted by significant functional and emotional challenges resulting from SLE symptoms, side effects, and complications, including anxiety, depression, mood disorders, and decreased health-related quality of life (HRQOL),[27-55] which further heightens service utilization costs; 2) Targeting racial disparities in SLE. In the United States, the highest lupus morbidity and mortality rates are among African American women.[3,56,57] SLE affects approximately 1 in 250 African American women of childbearing age, and African Americans overall have three to four times greater prevalence of lupus, risk of developing lupus at an earlier age, and lupus-related disease activity, damage, and mortality compared with Caucasians.[58-72] 3) Acknowledging challenges in SLE disease self-management. Evidence-based self-management interventions designed to enhance social support and provide health education, among lupus patients, have reduced pain, improved function, and delayed disability,[64,73-110] but African Americans and women are still disproportionately impacted by lupus.[45-50,55,58,59,111] Persistent disparities may be due to the non-responsiveness of existing programs to the unique needs of African Americans and/or women with lupus. In studies of predominantly low income and minority populations, peer mentors have been shown to help support healthy behaviors including breast feeding, smoking cessation, increased physical activity, and maintenance of weight loss,[112-131] along with improve medication adherence and blood glucose monitoring in people with diabetes.[132-141] There is some evidence that peer mentoring has also led to improvements in positive affect, sleep, social coping, and perception of bodily pain in rheumatic conditions.[142-145;90,146-154] In the MCRC/SCTR-funded Peer Approaches to Lupus Self-management (PALS) peer mentoring pilot study, mentees showed a trend toward lower disease activity, higher quality of life, lower pain symptoms and higher social support

(effect sizes >0.3) following participation in the intervention. In addition, both mentees and mentors gave very high scores for perceived treatment credibility and service delivery.[155] and 4) Proposing a lay patient navigator/care coordinator as an effective strategy to enhance self-management and improve outcomes. The Care Coordinator role has emerged in recent years as an important means of achieving significant outcomes for patients, their families, and the larger health system. These outcomes include increased patient satisfaction with service provision, an increase in patient access to services, and a decrease in the hospital length of stay and unplanned readmission. The most effective care coordination interventions are focused on providing holistic, relationship-based care.[156-174] The proposed lay patient navigator/care coordinator for patients with SLE builds on findings that the success of relationship-centered peer mentoring has been attributed to the non-hierarchical, reciprocal relationship that is created by sharing similar experiences and the tendency of peer mentoring relationships to be consistent with the individual's social and cultural beliefs,[175-177] making this the ideal interventional approach for this unique population.

Innovation

This study will provide preliminary evidence on the cost-effectiveness of a lay patient navigator/care coordinator for patients with SLE, targeting inpatient admissions to prevent readmissions as a marker of failed self-management. Our rationale is that a lay patient navigator/care coordinator integrated into the health care team to provide modeling and reinforcement to SLE patients will encourage patients to engage in activities that promote the learning of disease self-management skills and support their practice of these learned skills. This will lead to improved health-related quality of life, self-management, and disease activity and associated reductions in healthcare costs. Recently, the Department of General Internal Medicine at MUSC reported ~$3M in cost savings with respect to length of stay and 30 day readmission as a result of dedicated sickle cell nurse navigators/care coordinators on their primary care team. The project is innovative because it will be the first study of its kind in this field to test use of a lay patient navigator/care coordinator as a means of sustaining and expanding health improvements and corresponding cost savings associated with peer mentorship. Despite the proliferation of patient navigation programs across the United States, information related to the economic impact and sustainability of these programs is lacking.[170] Given the success of the peer mentoring approach in other chronic conditions that disproportionately impact minorities, and its responsiveness to the needs of this unique population, demonstration of a cost-effective and feasible means of sustaining benefits could result in health improvements that have not been attainable with other interventions. This would significantly reduce disparities and have considerable public health impact. The immediate goal of proposed work is to provide data on cost savings, cost effectiveness, and patient outcomes to refine approaches, service components, and measures, for future grants. Once effectiveness of the program is demonstrated, the long-term goal is to disseminate this potentially cost-effective approach in diverse clinical and community settings.

C. PRELIMINARY STUDIES

Provide an account of the principal investigator's preliminary studies pertinent to this protocol and/or any other information that will help to establish the experience and competence of the investigator to pursue the proposed project.

Investigative Team. This multidisciplinary team is well qualified to carry out the proposed study, and brings complementary expertise in lupus, health outcomes/health disparities, and biostatistics. Dr. Williams is a new minority investigator who has recently completed her K01 award (Grant number 1K01AR060026). Her team of senior investigators complement her expertise and will provide senior insight and support for this grant. The team has worked together on both her K01 and a previous pilot study, and includes an early career health disparities PI (Dr. Williams), and a physician and senior researcher in the area of rheumatology (Dr. Oates), who will continue to mentor Dr. Williams and oversee project activities. A senior biostatistician (Dr. Wolf) and a health economist (Dr. Dismuke) will provide expertise concerning data management, data programming, and statistical analyses. The lay patient navigator/care coordinator will be integrated into the health care team, with the support of the research team. As will be detailed below, this application represents a logical extension of the group's program of research geared toward improving outcomes for African American women with SLE.

The Balancing Lupus Experiences with Stress Strategies (BLESS) intervention (ClinicalTrials.gov Identifier: NCT01351662) validated a stress management program and assessed its effectiveness in reducing perceived and biological indicators of stress in 30 African American lupus patients participating in the SLE Clinic Database Project at MUSC. The intervention included 6 weekly, group sessions (n=15) of

the "Better Choices, Better Health" Chronic Disease Self-Management Program (CDSMP). The patients randomly assigned to the control condition (n=15) received general disease information and relevant literature. Pre, post, and follow up (3-4 months post-intervention) measures were collected in all patients to assess the effectiveness of the program. Overall, we found that patients who received the intervention reported improved self-efficacy pertaining to coping with having lupus, less health distress, post intervention, and lower levels of depression, compared with controls, and concluded that the intervention workshops acted to reduce perceived stress and improve quality of life.[73-75]

Our Intervention to Improve Quality of life for African-AmericaN lupus patients (IQAN) (ClinicalTrials.gov Identifier: NCT01837875) was an RCT that assigned 50 subjects each to one of three treatments groups: 1) a unique 'a-la-carte' self-management program with individualized intervention plan (IIP) including a mail-delivered arthritis kit, addition and access to a message board, participation in a support group, and enrollment in a local self-management program; 2) a 'set menu' that offered a standardized chronic disease self-management program only; and 3) a control group that received usual care (UC).[204] At 6 months of follow up, the 'a-la-carte' group had significant improvements in lupus disease activity, QOL, and stress/pain management compared to the control group. However, <50% of subjects completed intervention sessions and ~50% completed all follow-up assessments. Based on feedback from subjects in the BLESS study, the most valued aspect of the program was interaction with their peers, so the low completion rate in IQAN may have been due to absence of peer support.

The Peer Approaches to Lupus Self-Management (PALS) Pilot Study. Based on results of BLESS and IQAN studies as noted above, feedback from patients, and extensive review of the literature, the next logical step was an examination of peer mentorship as an alternative strategy to improve outcomes in this population. The intervention was piloted with African American women with lupus enrolled in the SLE database at MUSC. Seven mentors were trained and paired with 21 mentees to provide modeling and reinforcement to participants by telephone for at least 60 minutes every week for 12 weeks. Mentee outcomes of self-management, disease progression (including disease activity, damage, and cytokine balance) were obtained at baseline, mid-intervention (6 weeks from baseline), and immediately post-intervention (12 weeks from baseline), using validated tools. Qualitative data were also collected over the course of the study in the form of weekly mentee check-ins, mentor logs, and an end-of study focus group. We deemed a controlled trial for the pilot phase unnecessary because: 1) Randomization is expensive and not likely to demonstrate differences in small sample sizes; 2) Pilots are meant for proof of concept, feasibility and to detect likely effect sizes; and 3) In our pilot intervention with a sample size of n=30, we observed significant effects, feasibility, acceptability, and signal of efficacy in key outcomes. At mid-intervention (6 weeks from baseline), mentees showed a trend toward lower disease activity, higher quality of life, lower pain symptoms and higher social support. At post-intervention, we observed statistically significant decreases in patient-reported disease activity (significant change score of 24.70 or 25% change in patient global assessment of overall lupus disease activity, $p<0.001$), incrementally improving trends in patient activation, and statistically significant decreases in depression (significant change score of 2.62 or 11% change in PHQ-8 score, $p=0.05$) and anxiety (significant change score of 3.52 or 15% change in GAD-8 score, $p=0.018$). In addition, both mentees and mentors gave very high scores for perceived treatment credibility and service delivery, providing preliminary support for the efficacy, acceptability, and perceived credibility of the PALS intervention.[155]

Lessons Learned: Preliminary data support the efficacy, acceptability, and perceived credibility of the PALS intervention. However, we found that weekly mentee/mentor contact was challenging, so we have adapted the current grant to have bi-weekly meetings. Feasibility/acceptability assessments and qualitative feedback indicated that mentor-mentee load (1:3 mentor:mentee ratio) and the time mentoring pairs spent interacting were appropriate. Major concerns of our study population emerged as three main qualitative themes: a) interpersonal, familial and romantic relationships; b) individual experiences of living with SLE; and c) physician-patient relationships. We also found that: 1) empowerment was facilitated/achieved by mentors taking their mentorship responsibilities seriously and seeking several avenues for collaboratively developing success with their mentees; 2) mentors felt empowered through exchanges with mentees in terms of being able to discuss topics that they felt were often marginalized by healthcare professionals; and 3) one of the most important findings from the qualitative data centered on the intervention's encouragement of reciprocity. Some participants highlighted that although they did not have "expertise" with specific topics, the structure of the intervention allowed for collective learning and consequently empowerment in relation to patient-physician encounters.[205-206] Finally, we found that a one month run-in period for mentors to work through call scheduling, practice intervention delivery over

the phone and establish processes for follow-up was also essential to the success of the program. These lessons learned have been incorporated into the processes for the current proposal.

Summary of Preliminary Data and Lessons Learned
Our prior research experiences with African American women with SLE have demonstrated that self-management education delivered in weekly sessions led to improvements in lupus self-efficacy, health distress, and depression, but that more culturally targeted information and increased social support could yield more significant improvements in quality of life. More importantly, results of BLESS and IQAN studies, feedback from patients, extensive review of the literature and preliminary data from the PALS pilot study suggest that a peer mentoring intervention is credible, acceptable and likely to be effective at improving self-management, decreasing disease activity and improving quality of life in African American women with SLE.

D. RESEARCH DESIGN AND METHODS (including data analysis)

Describe the research design and the procedures to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted and specify what statistical methods will be used. Describe any new methodology and its advantage over existing methodologies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. As part of this section, provide a tentative sequence or time-table for the project. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

Overview of Study Design. The Care-coordination Approach to Learning Lupus Self-Management (CALLS) study is a double arm, pre-post pilot designed to examine whether modeling and reinforcement from a lay patient navigator/care coordinator improves disease self-management, indicators of disease activity, health related quality of life (HRQOL), and 30-day readmission in SLE inpatient admissions. We will recruit 40 patients (20 questionnaires and phone sessions and 20 questionnaires only) with active SLE upon hospital admittance at the Medical University of South Carolina (MUSC). The lay patient navigator/care coordinator will be trained to deliver intervention content by twelve weekly telephone sessions carried out across the course of the study. All participants will be assessed using validated measures of patient reported outcomes at baseline, mid-intervention (6 weeks post-enrollment), and immediately following the intervention (12 weeks post-enrollment). Outcomes for patients who agree to phone sessions will be compared with the outcomes of patients who opt to participate in questionnaires only. The study will last 12 months with recruitment and enrollment over 6 months, 3 months for intervention delivery and 3 months for data analysis.

Study Population. The total number of individual patients with systemic lupus erythematosus (SLE) currently being followed by clinicians at MUSC is 1,159 in the past six months that had this encounter diagnosis and 1,526 with this diagnosis in the chart history or problem list or encounter diagnosis, of which approximately 60% are African American and 90% are female. This will allow for the assessment of impact and cost savings/effectiveness according to underrepresented racial and gender categories. The target population for this study will be SLE inpatient admissions. There are approximately 35 SLE and Scleroderma hospital admissions each month, so it is expected that over a 3-month recruitment period, we will be able to recruit 40 participants (20 questionnaires and phone sessions and 20 questionnaires only).

Recruitment of Lay Patient Navigator/Care Coordinator
The PI will identify a suitable lay patient navigator/care coordinator based on their maturity, emotional stability, and verbal communication skills. Suitable candidates will have at least a high school diploma or equivalency with at least one year of patient care experience in a health care facility; or a Certified Nursing Assistant; or successful completion of a Nursing Assistant or Medical Assistant course at an accredited institution or equivalent training; or EMT or Paramedic certification; or a Bachelor's degree. They will possess the ability to understand and implement a variety of detailed instructions in the execution of therapeutic procedures and the ability to make accurate physical observation of patients. Candidates must communicate effectively both verbally and in writing. Potential lay patient navigators/care coordinators will also understand that the position may require working irregular hours under stressful conditions, holidays and weekends. Within two months of date of hire, the selected candidate will be expected to successfully pass the online course modules and skills validation for basic skills. They will be expected to have reliable attendance, and are responsible for maintaining their Basic Life Support (BLS) and any other annual competencies. Since mentoring from peers can establish trust and in turn decrease disparities in health care outcomes[178] and peers who have experience managing their lupus may be in a better position than those without the condition to share knowledge and experience that others may not be able to relate to, the ideal candidate will have lupus or be a family member or friend of someone with lupus. Thus, additional considerations include: 1) disease duration > 2 years; 2) considered competent in the management of their conditions as

assessed by the PI (Williams) and clinical consultant (Oates); 3) able to attend scheduled training sessions; 4) at least some college due to the fact that their role that involves counseling, modeling, and delivering education; and 5) willing to provide one-on-one support to patients with SLE. We already have identified four candidates as a potential lay patient navigator/care coordinator.

Recruitment of SLE patients
Admitted SLE patients will be referred by their physician for participation in the study, who will provide a letter that will explain the study and provide participants a number to call if they have questions or concerns prior to agreeing to participate. Participants who indicate interest in the study will be immediately screened for eligibility, and if eligibility criteria are met, informed consent will be obtained. Once a patient has been consented, they will be randomized to membership in one of the two study arms. assigned to the intervention (complete questionnaires and phone sessions) or control (complete questionnaires only) arm, and the rest of the recruitment visit will include baseline self-report assessments and scheduling of phone sessions (if applicable). Preliminary data from our group suggests that those participants with the worse outcomes at baseline experienced the largest gains post-intervention, so the proposed intervention focuses on patients with high needs (as indicated by hospital admission) to reach those with the greatest potential for benefit from supportive services. This approach could ultimately incorporate the lupus nephritis risk prediction model/tool being developed by Dr. Oates to prevent renal failure and admissions due to renal flares.

Inclusion criteria for SLE patients include: 1) Hospital admission for SLE-related issue; 2) clinical diagnosis of systemic lupus erythematosus (SLE) from a physician; 3) 18 years of age or older; 4) able to provide informed consent and take part in ongoing assessment/evaluation activities (self-reported questionnaires); 5) able to commit to duration of study (3 months); 6) able to communicate in English; and 7) have an active phone line (landline or cell phone) for the duration of the study, if agreeing to phone sessions with the lay patient navigator/care coordinator. Exclusion criteria include: 1) cognitive impairment; 2) acute decompensation of chronic conditions precluding participation; 3) conditions that preclude participation in assessments (e.g. blindness or deafness); and 4) terminal illness or life expectancy less than 6 months as evaluated by physician.

Lay Patient Navigator/Care Coordinator Service Elements.
Training: Peer mentors are usually individuals who have successfully coped with a similar condition as their mentees.[179-183] In formal interventions, mentors receive training focused on communication skills, including empathetic listening, helping mentees clarify life goals, and problem solving with the aim of having the mentor support the mentee.[175,184] Similarly, upon hire, the lay patient navigator/care coordinator will receive six hours of training and participate in a week of practice role-playing, followed by another six hours of training, prior to working with patients.[185] The lay patient navigator/care coordinator will be given a written manual presenting all material in detail for their ongoing reference. Navigator/Coordinator training will emphasize how to provide support and will include development of skills to facilitate conversations about SLE, SLE-related behaviors, thoughts, and feelings, and the nature of recommended treatments, as well as to alleviate the patient's sense of isolation by giving them the opportunity to discuss their condition with someone who has shared the experience; to enhance and reinforce the patient's sense of self-efficacy to manage their condition; and to encourage the patient to participate actively in the recommended self-management skills building therapy.
Phone sessions: The CALLS program will focus on enhancing the health of SLE patients, with emphasis on patient empowerment and promoting proactive participation in health care. Recruitment and enrollment will occur on a rolling basis, and the program will consist of 12 weeks of service delivery that will include one standard educational session by telephone or in-person meeting every week. The weekly educational session will be generally structured in three parts: introduction, structured education, and problem solving. Weekly content will be adapted from the twelve modules of the Peer Approaches to Lupus Self-management (PALS) study,[155] and further tailored according to prominent barriers to care in the scientific literature.[186] Content will include: 1) Medication adherence; 2) Communication with provider; 3) Patient engagement; 4) Recognizing and treating depression; 5) Overcoming socioeconomic barriers; 6) Social Support network; 7) Appointment/ Lab adherence; and 8) Transportation. The lay patient navigator/care coordinator will respond to individual patient needs by tailoring intervention content to personal requirements and facilitating care coordination and will be able to address insurance, financial, and logistical issues (e.g., transportation, appointment scheduling, child or elder care), while providing understandable health education that may lessen fears of SLE diagnosis and treatment.[174] Lay patient navigator/care coordinator activities will be guided by frequent self-report assessments, which will help to identify patient concerns across multiple domains, triage patients to appropriate resources, and ultimately overcome barriers to health care. The lay patient navigator/care coordinator can use baseline data collected prior to phone sessions to describe preliminary patient themes (i.e., disease activity and damage, depression, medication adherence, communication with provider, patient engagement) and subsequent assessments can be used to track progress. Based on our experiences with the MCRC/SCTR-funded Peer

Approaches to Lupus Self-management (PALS) peer mentoring pilot study, we are fairly certain that 100% of scheduled sessions will occur and that participants will be compliant and responsive to educational content.

Treatment Fidelity. Drs. Williams and Oates will deliver training for the lay patient navigator/care coordinator at the onset of the study. They will be given parameters for their roles and instructed on how to handle potential issues that may arise. After the initial training, the lay patient navigator/care coordinator will continue to meet with the PI weekly to identify challenges and reinforce the guidelines for their role.[185] They will be required to submit logs of the number of calls made, number of hours spent with patients, and content covered during that week. Self-report assessments will be used to track the effectiveness of their services.

Data Collection Schedule. Study questionnaires were carefully chosen based on available evidence of previous validation and their ability to measure key elements of the study aims. The primary method of data collection will be face-to-face interview. All study visits will take place in an MUSC affiliated hospital, the Research Nexus or comparable private location on the campus of MUSC. Indicators of medication adherence will be extracted from the electronic medical records. Financial data will be extracted from the research data warehouse for historical and patient-specific data for cost effectiveness. The MUSC REDCap system will be used for data management.

Primary Outcomes. Primary outcomes of quality of life, self-management, and disease activity (including medication adherence) will be measured using the Lupus Quality of Life Questionnaire (LUP-QOL), which incorporates the Medical Outcomes Study (MOS) Short Form 36 Health Survey (SF-36) and the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F);[187-189] the Patient Activation Measure (PAM), [190,191] which assesses an individual's knowledge, skill, and confidence for managing their health and healthcare; medication refill data in electronic medical records to further validate treatment engagement/adherence; 30-day readmission data to assess cost savings or deficit (compared to historical data from the prior year); and the Systemic Lupus Activity Questionnaire (SLAQ),[192] which is based on items from the physician-rated Systemic Lupus Activity Measure (SLAM) that could be self-reported.[193,194]

Process Measures and Secondary Outcomes. To assess for differences in outcome expectancy, a modified treatment credibility scale developed by Borkovec and Nau (1972) will be used. Satisfaction with Care will be measured with a previously validated general scale to measure satisfaction/dissatisfaction with health care. Other covariates will be measured by previously validated items from the 2002 National Health Interview Survey [NCHS 2004] to capture age, marital status, education, household income, and health insurance; the Chew Health Literacy Screening Survey[195] to detect potential health literacy problems; the Arthritis Self-Efficacy Scale pain and other symptoms sub-scale, arthritis.[196,197] which measures confidence in one's ability to manage the pain, fatigue, frustration, and other aspects of disease; the PHQ-9, which scores each of the 9 DSM-IV criteria for depression;[198,199] and the 7-item General Anxiety Disorder scale (GAD-7).[200]

Analysis Plan
Aim 1 - Feasibility analyses: Important measures of feasibility will include recruitment, compliance, non-response proportions and participant satisfaction. We will use 95% confidence intervals (CI) for proportions to estimate the proportion of participants who agree to participate out of the number who are initially approached, the proportion who are compliant with the treatment protocol, and the proportion who exit the study prematurely (drop out). In addition, frequency distributions describing the participants' reasons for noncompliance and discontinuation of study participation will be developed. We will also evaluate patient satisfaction with the lay patient navigator/care coordinator services using a likert-type satisfaction scale. For the continuous feasibility measures (e.g. treatment credibility, treatment adherence, phone sessions and attrition), frequency distributions and the median and mean responses (with 95% CIs) will be obtained.

Aim 2 - Estimation of effect sizes for calculating sample size for future R01: Analyses for Aim 2 of the pilot/feasibility study will focus on estimation of preliminary effectiveness as determined by: (a) change in quality of life; (b) change in self-management; and (c) change in disease activity (self-reported). Estimates of effect sizes for outcome variables will be reported as point estimates (mean differences between pre-post measures, as appropriate) and interval estimates (95% CI) to provide a preliminary indication of the presence of a clinically important treatment effect.[201-203] After studying the distributions of baseline characteristics, we will use a linear mixed-effects regression model to estimate the difference in the change from baseline between the two groups. Least squares means for each outcome variable will be compared at the primary time point (week 12) and at intermediate time points (week 6 or 12) using model contrasts to estimate the corresponding 95% CI for the estimates of the difference in outcome means (effect sizes) between and within treatment group.

Aim 3 – Collection of resource use and cost information: With a total of 40 patients, and 20 patients in the intervention group, we expect a maximum of 6-8 readmissions over 30 days. If the readmission rate was reduced from 20% to 15%, there would only be about 7% power to detect a difference. Further, the mean cost of lupus admissions is about $17,000, but the SD of these costs is around $30,000, which indicates that it is not feasible to expect to detect a difference in cost between the groups. However, there is a large amount of resource use and cost information that will be collected to inform a well-designed economic study of the cost-effectiveness of the use of lay-navigators for SLE patients in the acute care setting. To plan a larger trial with an economic component, the following pilot data will be collected: 1) resource use and cost of training the navigator; 2) cost of use of the navigator for 12 weeks; 3) any issues related to recidivism of patients once they no longer have the navigator support; 4) association between length of stay (LOS) of the initial admission and subsequent readmissions; 5) total number of admissions and days in the hospital for the 12 week intervention period (some patients have more than one readmission within 30 days of discharge and at least 50% of readmissions over 90 days happen after the 30-days benchmark); 6) use of other services, such as ER visits; 6) distributions of cost for the medical care resources used; 7) other medical care resources of importance to patients; 8) economic and financial barriers to use of care outside the hospital setting; and 9) how much of the care resources that patients use during the study period is missed because patients get care from other hospitals or entities who are not part of the MUSC record system. For collection and analysis of pilot data, resource use and cost data will be accessed through the Services, Pricing, and Application for Research System (SPARC Requests), which is available to MUSC-based investigators under MUSC's Clinical and Translational Science Award (CTSA). The system allows for easy access to pricing for services across the MUSC campus and its providers and focuses on billing compliance and budgetary analysis. In order to extract data from the MUSC record systems, services are requested through an online portal and data is then provided through direct consultation. Within the SPARC system, members of the study team will also be able to track service utilization and pricing throughout the duration of the study.

Sample Size Justification: The primary goal in Aim 1 is to estimate the proportion of participants who are compliant in the two groups. A sample of 20 subjects per group provides a 95% confidence interval for compliance within group with a width < 0.46 assuming at least 50% compliance. Compliance is anticipated to be greater than 50% which will yield a more precise estimate. The primary goal in Aim 2 is to estimate the change in LUP-QOL between baseline and 12 months post intervention within and between each treatment. Mean change from baseline with group and the difference in change between groups will be estimated using contrast statements from a linear mixed model of LUP-QOL score with fixed effects for treatment, time, and the treatment by time interaction and a random subject effect. A sample of 20 participants measured at 3 time points and assuming an AR(1) correlation with p=0.5 allows us to estimate a two-sided 95% confidence interval for change in LUP-QOL from baseline within group to within 0.57 standard deviations (1). A sample size of 20 subjects per treatment group also allows us to estimate a 95% confidence interval for the difference in change in LUP-QOL from baseline between the two groups to within 0.64 standard deviations from the mean assuming common standard deviation between the groups.

E. PROTECTION OF HUMAN SUBJECTS

1. RISKS TO THE SUBJECTS

a. Human Subjects Involvement and Characteristics

- Describe the proposed involvement of human subjects.

- Describe the characteristics of the subject population, including their anticipated number, age range and health status.

The overarching aims of this pilot project is to provide preliminary evidence on the cost-effectiveness of a lay patient navigator/care coordinator for patients with SLE, targeting inpatient admissions to prevent readmissions as a marker of failed self-management. Our rationale is that a lay patient navigator/care coordinator integrated into the health care team to provide modeling and reinforcement to SLE patients will encourage patients to engage in activities that promote the learning of disease self-management skills and support their practice of these learned skills. This will lead to improved health-related quality of life, self-management, and disease activity and associated reductions in healthcare costs.

Patient eligibility criteria: The study inclusion and exclusion criteria are as follows:

Inclusion criteria for SLE patients include: 1) Hospital admission for SLE-related issue; 2) clinical diagnosis of systemic lupus erythematosus (SLE) from a physician; 3) 18 years of age or older; 4) able to provide informed consent and take part in ongoing assessment/evaluation activities (self-reported questionnaires); 5) able to

commit to duration of study (3 months); 6) able to communicate in English; and 7) have an active phone line (landline or cell phone) for the duration of the study, if agreeing to phone sessions with the lay patient navigator/care coordinator. Exclusion criteria include: 1) cognitive impairment; 2) acute decompensation of chronic conditions precluding participation; 3) conditions that preclude participation in assessments (e.g. blindness or deafness); and 4) terminal illness or life expectancy less than 6 months as evaluated by physician.

Targeted/Planned Enrollment Table

Total Planned Enrollment 40

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
	Sex/Gender		
Ethnic Category	Females	Males	Total
Hispanic or Latino	2	1	3
Not Hispanic or Latino	34	3	37
Ethnic Category: Total of All Subjects*	40		
Racial Categories			
American Indian/Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	29	3	32
White	7	1	8
Racial Categories: Total of All Subjects*	36	4	40

**The "Ethnic Category: Total of All Subjects" must be equal to the"Racial Categories: Total of All Subjects".*

- Identify the criteria for inclusion or exclusion of any subpopulation.
- Explain the rationale for the involvement of special classes of subjects, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. Note that 'prisoners' includes all subjects involuntarily incarcerated (for example, in detention centers) as well as subjects who become incarcerated after the study begins.
- If you propose to exclude any sex/gender or racial/ethnic group, include a compelling rationale for the proposed exclusion. For example, 1) the research question addressed is relevant to only one gender or 2) evidence from prior research strongly demonstrates no difference between genders.
- Provide either a description of the plans to include children or, if children will be excluded from the proposed research, then you must present an acceptable justification for the exclusion. For example, 1) the condition is rare in children as compared to adults or 2) insufficient data are available in adults to judge risk in children.
- List any collaborating sites where human subjects research will be performed, and describe the role of those sites in performing the proposed research.

African Americans display the highest rates of lupus. Due to the exposure of African Americans to a unique trajectory of stressors throughout the life course, it may be critical to test patient navigation as an alternative strategy to improve outcomes in this population. Given the success of the peer mentoring approach in other chronic conditions that disproportionately impact minorities, and its responsiveness to the needs of this unique population, this intervention could result in health improvements that have not been attainable with other interventions. This would significantly reduce disparities and have considerable public health impact.

In the United States, the highest lupus morbidity and mortality rates are among African American women. SLE affects approximately 1 in 250 African American women of childbearing age. Very few men are affected by the disease with a general ratio of 10 females to every 1 male with SLE.

b. Sources of Materials
- Describe the research material obtained from living human subjects in the form of specimens, records, or data.
- Describe any data that will be recorded on the human subjects involved in the project.
- Describe the linkages to subjects, and indicate who will have access to subject identities.
- Provide information about how the specimens, records, or data are collected and whether material or data will be collected specifically for your proposed research project.

1. Research Material & Data: Sources of research material include medical records and research questionnaires.
2. Linkages to Subjects: Subjects will provide identifying information in addition to research data. Paper documents pertaining to this study will be stored in locked file cabinets in both the clinical center and the data

management center, and data will be entered into secure, password-protected web databases developed for this study. A database of name, contact address, telephone number, and other research identification numbers will be stored separate from the study database, for purposes of audit by the MUSC IRB, if necessary. Access to study data will be limited to research personnel.
3. Collection of Data and Specimens:
Personnel: A part-time lay patient navigator will be responsible for consent, enrollment and data collection, a part time health economist will be responsible for accessing and analyzing resource use and cost data, and a part-time data coordinator (DC) will be responsible for data management and analyses for patient reported outcomes.
Data Collection Schedule: At the baseline visit, the lay patient navigator will give detailed explanation of the study, the reimbursement schedule, and obtain consent. Participants will complete a questionnaire that captures demographics, health literacy, coping, disease activity, disease self-management, anxiety, depression, and quality of life. The lay patient navigator will review study goals, establish the schedule of study sessions, obtain contact information (primary and alternate telephone numbers), and receive study materials. After the baseline assessment, follow-up assessments will be conducted at 6 weeks and 12 weeks. As much as possible, research visits will be scheduled on the same day as their clinic visit.

c. Potential Risks
- Describe the potential risks to subjects (physical, psychological, social, legal, or other), and assess their likelihood and seriousness to the subjects.
- Where appropriate, describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures to participants in the proposed research.

Potential risks to the patient include possible violation of the patient's privacy, discomfort with questions on the research questionnaire, and psychological distress. Details on how these risks will be minimized are discussed under adequacy of protection against risks below.
Confidentiality: This will be maintained by keeping participant folders in locked file cabinets in the research center. Only participants' unique identification numbers will be recorded in folders and on data forms. The database will remain on the MUSC computer system that use unique ID numbers, rather than names, and will be password-protected.

2. ADEQUACY OF PROTECTION AGAINST RISKS

a. Recruitment and Informed Consent
- Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.
- Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent.

After obtaining approval from the IRB, admitted SLE patients will be referred by their physician for participation in the study, who will provide a letter that will explain the study and provide participants a number to call if they have questions or concerns prior to agreeing to participate. Participants who indicate interest in the study will be immediately screened for eligibility, and if eligibility criteria are met, informed consent will be obtained. Once a patient has been consented, they will be randomized to membership in one of the two study arms. assigned to the intervention (complete questionnaires and phone sessions) or control (complete questionnaires only) arm, and the rest of the recruitment visit will include baseline self-report assessments and scheduling of phone sessions (if applicable).

b. Protection against Risk
- Describe planned procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
- Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.
- Studies that involve clinical trials (biomedical and behavioral intervention studies) must include a description of the plan for data and safety monitoring of the research and adverse event reporting to ensure the safety of subjects in Section 4 below.

Given the complexity of SLE and the overall study goal to provide modeling and reinforcement by a lay patient navigator to lupus patients to encourage them to engage in activities that promote the learning of disease self-

management skills and support their practice of these learned skills, every attempt will be made to ensure that the study/navigation does not negatively impact the patient. To address this potential concern the following approach will be implemented:

1. Upon hiring, lay patient navigators will receive training, prior to working with patients.
2. Lay patient navigators will be given a written manual presenting all the material in detail for their ongoing reference.
3. Lay patient navigators will be given parameters for their roles and instructed on how to handle potential issues that may arise (e.g. not providing clinical advice) along with role-playing.
4. After the initial training, the lay patient navigator will continue to meet with the PI weekly to identify challenges and reinforce the guidelines of the study. During these meetings, the PI will also monitor the lay patient navigator's comfort with interactions with patients. If the lay patient navigator express discomfort and/or feeling overwhelmed, the study will be terminated.
5. Weekly phone calls to patients and PI meetings with the lay patient navigator will be used to track participant satisfaction with the navigation process.

Additional protections against potential risks include the following:

1. Psychological Distress: Because we will be administering a questionnaire that measures the presence of depression, we will take several steps to ensure the safety of research participants. Research personnel will be trained by the PI to identify patients who meet criteria for depression on the PHQ-9. Participants who screen positive for depression will be assessed by a clinician before leaving their study visit to ensure their well-being and verbally instructed to seek care from their PCP. If deemed appropriate, they will also be given the Suicide Prevention National Hotline, 1-800-SUICIDE (784-2433), and told to call if they experience acute worsening of symptoms before they can be seen by their PCP.
2. Administration of Research Questionnaires: Some participants might be offended by detailed questions about emotional or physical health status and impairment. All participants will be informed at the outset that they may terminate participation at any point. Past research suggests that data collection using these measures can be conducted without undue psychological distress or exacerbation of symptoms among study participants.
3. Unknown risks: Participation in research may have other unknown risks. The researchers will advise participants if they learn of emerging information that might alter participants' decisions to participate.

Participants requiring medical or other professional intervention for study-related events will be provided with appropriate and timely medical guidance by the PI. If adverse events occur during the conduct of this study, they will be reported to the MUSC IRB in accordance with Section 4.7 - Unanticipated Problems and Adverse Events Policy and Procedures.

To protect against the potential risk of loss of confidentiality and/or breach of privacy, data will be compiled using codes in lieu of personal identifiers. Access to study data will be limited to research personnel. Development of and security oversight for the electronic database for this study will be performed by the PI and study statistician. Paper documents pertaining to this study will be stored in locked file cabinets and electronic data will be entered into secure, password-protected databases developed for this study by the research assistants. The PI will perform periodic review of the data entry process to ensure accuracy of recording. When study results are published or presented, only aggregate reports of the results will be used and participants' identity will not be revealed. A file of name, contact address, telephone number, and other research identification numbers will be stored separately on paper and on computer, for purposes of audit by the MUSC IRB, if necessary.

In the event of negative interactions between the lay patient navigator/care coordinator and patients, the following steps will be taken:

1. The PI will communicate with patients and the lay patient navigator on a weekly basis to assess calling patterns, content of calls, any other interactions between the lay patient navigator and patient(s), and any concerns either may have.
2. Patients and the lay patient navigator will be encouraged to contact the PI at any time if they run into a difficult situation with a patient. If during such communication, patient or the lay patient navigator reports that they believe that their patient/lay patient navigator may be depressed, homeless/displaced, suicidal, has broken confidentiality, is repeatedly asking for medical advice, prying too much into their personal life, or that they are simply not connecting, the PI will meet with each party individually to discuss, troubleshoot, and develop solutions or direct to services, when applicable.
3. If the patient/lay patient navigator does not resolve the issue successfully on their own (with the exception of issues of suicidality, depression, and homelessness, which they are instructed to turn over to the PI to handle/address), the PI will meet with the pair together to discuss, troubleshoot, and develop solutions.

4. If the patient and lay patient navigator agree to continue, but report that issues can/have not been resolved, the PI will remove that patient from the study.
5. If complaints persist about a specific patient or the lay patient navigator that contradict study procedures (e.g., breaking confidentiality, not adhering to intervention format), that participant could be asked to leave the study. If multiple patients express discontent with the lay patient navigator, the study will be terminated.

3. POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE SUBJECTS AND OTHERS

- Discuss the potential benefits of the research to the subjects and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

The overarching aims of this pilot project is to provide preliminary evidence on the cost-effectiveness of a lay patient navigator/care coordinator in forty (40) systemic lupus erythematosus (SLE) patients, targeting inpatient admissions to prevent readmissions as a marker of failed self-management. Our rationale is that a lay patient navigator/care coordinator integrated into the health care team to provide modeling and reinforcement to SLE patients will encourage patients to engage in activities that promote the learning of disease self-management skills and support their practice of these learned skills.

4. IMPORTANCE OF THE KNOWLEDGE TO BE GAINED

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.
- NOTE: Test articles (investigational new drugs, devices, or biologicals) including test articles that will be used for purposes or administered by routes that have not been approved for general use by the Food and Drug Administration (FDA) must be named. State whether the 30-day interval between submission of applicant certification to the FDA and its response has elapsed or has been waived and/or whether use of the test article has been withheld or restricted by the Food and Drug Administration, and/or the status of requests for an IND or IDE covering the proposed use of the test article in the research plan.

The proposed pilot study if successful will lead to improved health-related quality of life, self-management, and disease activity and associated reductions in healthcare costs. The project is innovative because it will be the first study of its kind in this field to test use of a lay patient navigator/care coordinator as a means of sustaining and expanding health improvements and corresponding cost savings associated with peer mentorship. Despite the proliferation of patient navigation programs across the United States, information related to the economic impact and sustainability of these programs is lacking.[170] Given the success of the peer mentoring approach in other chronic conditions that disproportionately impact minorities, and its responsiveness to the needs of this unique population, demonstration of a cost-effective and feasible means of sustaining benefits could result in health improvements that have not been attainable with other interventions. This would significantly reduce disparities and have considerable public health impact.

5. SUBJECT SAFETY AND MINIMIZING RISKS (Data and Safety Monitoring Plan)

*Studies that involve *clinical trials (see description below) must include a description of the plan for subject safety and minimizing risks of the research, including data monitoring and adverse event reporting to ensure the safety of subjects. The complexity of the plan should be determined by the level of risk to subjects. The plan should specify: 1) what will be monitored, 2) how frequently the monitoring will occur, 3) who will be responsible for the monitoring, and 4) study endpoints.*

The data and safety monitoring plan will include an internal Data Safety Monitoring Committee (DSMC) and the institutional IRB. The purpose of the DSMC and IRB are to ensure the safety of participants and the validity and integrity of the data. The PI will monitor lay patient navigator and patient reports of their activities and communications to ensure that participants are safe and to detect any unexpected adverse events and report any concerns to the DSMC. Summaries of adverse events reports or patient safety concerns raised by the DSMC or IRB will be made to the respective funding agency in the annual progress report unless the nature of a particular event is such that it warrants immediate reporting.

DSMC: The DSMC will consist of a health disparities researcher, biostatistician, and a designated medical monitor (board certified rheumatologist who will have oversight on medical risks and review adverse events) who

are not affiliated with the project. The functions of the DSMC will include: 1) provide scientific oversight; 2) review all adverse effects or complications related to the study; 3) monitor accrual; 4) review summary reports relating to compliance with protocol requirements; and 5) provide advice on resource allocation. The DSMC will meet quarterly and as necessary by telephone. The recommendations of the DSMC will be reviewed and the PI will take appropriate corrective actions as needed.

Institutional IRB: The IRB will review and approve the funded protocol, review patient consent forms, ensure protection of patient privacy and safety, and monitor the study on an ongoing basis. Adverse events will be reported to the IRB as they occur. Annual reports to the IRB will indicate accrual rate, adverse events, new findings that may influence continuation of the study, and reports of the DSMC.

*Clinical Trials
A clinical trial *is a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).*
Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Behavioral human subjects research involving an intervention to modify behavior (diet, physical activity, cognitive therapy, etc.) fits these criteria of a clinical trial. Human subjects research to develop or evaluate clinical laboratory tests (e.g. imaging or molecular diagnostic tests) might be considered to be a clinical trial if the test will be used for medical decision-making for the subject or the test itself imposes more than minimal risk for subjects.

F. REFERENCES/LITERATURE CITATIONS

List all references. Each reference must include the title, names of all authors, book or journal, volume number, page numbers, and year of publication. The reference should be limited to relevant and current literature. It is important to be concise and to select only those literature references pertinent to the proposed research.

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G. CONSULTANTS

Where applicable, attach electronic versions of appropriate letters from all individuals confirming their roles in the project. Go to the application under "additional uploads" to attach this information.

H. FACILITES AVAILABLE

Describe the facilities available for this project including laboratories, clinical resources, etc.

Medical University of South Carolina (MUSC)
MUSC is the center of the state's largest medical complex located near the Ashley River on the western border of Charleston, SC. A free--standing academic health center, MUSC is the only tertiary/quaternary care referral center for the entire state. Within a four--block radius of MUSC are the Ralph H. Johnson VA Medical Center, Charleston County Health Department, Charleston Center community addiction treatment program, Roper/St. Francis Healthcare (the area's largest community hospital), and numerous health professional offices and services.

Education
MUSC is the oldest medical school in the southern United States, which was founded in 1824. MUSC now has six colleges: Medicine, Pharmacy, Nursing, Graduate Studies, Health Professions and Dental Medicine. The University is fully accredited by the Southern Association of Colleges and Schools (SACS) to award bachelor's, master's, doctoral and health professional degrees with further accreditation by JCAHO, LCME and other national, professional and specialized accrediting bodies. The teaching faculty on campus consists of ~1,200 full--time and >200 part--time members. MUSC offers professional education at undergraduate, graduate and postgraduate levels appropriate to the health care disciplines, awarding ~900 degrees annually with enrollment of >2,600 degree--seeking students. In addition, the university coordinates the training of approximately 80 interns, 400 medical/surgical residents and 100 specialty fellows in ACGME-- approved programs and dozens of dental and pharmacy residents.

Community
MUSC is the third largest agency in the state and the largest employer in the Charleston area with more than 13,000 employees in the University and Medical Center. MUSC also leads the South Carolina Area Health Education Consortium (AHEC), linking the academic health sciences center in Charleston to community--based health care centers statewide with an emphasis on health disparities, rural health and access to health care. SC AHEC has received national recognition for outstanding community service and leadership in innovative health services delivery and outreach programs, including the 2006 Eugene S. Mayer Award as the best model statewide AHEC system in the nation.

Department of Public Health Sciences (DPHS)
The DPHS, chaired by John Vena, Ph.D., has more than 55 faculty members with expertise in biostatistics, epidemiology and behavioral sciences. They collaborate with multiple investigators throughout the university. Faculty interests include both application and theory, particularly aspects of quantitative analysis relevant to health and health care delivery research. Faculty members in biostatistics have expertise in such areas as statistical genetics, categorical, longitudinal, multivariate, survival, and Bayesian analysis. They direct clinical trials and provide biostatistical collaboration to basic scientists, health services and clinical researchers. Faculty members with an emphasis in epidemiology have interests in cardiovascular disease, cancer, aging, diabetes, perinatal epidemiology, oral health, brain trauma, and other chronic diseases, including autoimmune connective tissue diseases. Faculty members have extensive external peer-reviewed funding. DPHS houses and supports two institutional research resource units: the Collaborative Unit and the Data Coordination Unit.

DPHS has a Local Area Network (LAN) with a dedicated manager, encompassing personal computers, file servers, printer servers, and other shared peripherals. Individual computers are managed centrally for software updates and network security. In addition, DPHS has in-house resources for high performance computing, including 15 dual processor servers with 32bit 3.1GHz processors, each with 4 GB RAM processors. In addition, an 8-blade server is in the early stages of assembly that will increase the number of high performance units to 48. Finally, a grid computing initiative has been started in order to make effective use of this computing infrastructure available to non-mathematicians. The scientific software licensed to the department includes MATLAB, Splus, MathCAD, SAS, Statistica, NQuery, and STATA. A variety of open source software for scientific computing is also widely used. In addition to the department webserver (http://www.biometry.musc.edu), DPHS hosts two webservers for interfacing with applications developed in the department – the bioinformatics infrastructure of the Marine Genomics Consortium (http://www.marinegenomics.org) and a recently configured infrastructure for miscellaneous bioinformatics resources (http://www.bioinformatics.musc.edu). In order to provide a stable, scalable infrastructure, the latter applications run under Linux UNIX with Apache webserver configured for Secure Socket Layer with 128-bit encryption. The department has full-time staff responsible for the procurement, installation, operation, and basic maintenance of hardware and software.

Collaborative Unit

The Collaborative Unit is a University Research Resource Facility (URRF) providing expert consultation in biostatistics, bioinformatics and epidemiology. Paul Nietert, Ph.D., directs the Collaborative Unit, which is housed in the DPHS. Services include assistance in: design of observational studies and experiments; selection of data collection instruments and data management systems; selection, application, interpretation, and reporting of epidemiological, biomathematical, environmental risk assessment, and statistical methods; graphical analysis of data; estimation of sample size; and selection of statistical, graphical and database software packages. The Collaborative Unit assists in preparing the biostatistical and epidemiological narrative associated with grant proposals, and with presentations and publications following the research. As a URRF, the Collaborative Unit receives institutional support to help faculty across campus develop competitive grant applications. The Collaborative Unit also provides a training experience for trainees interested in developing skills in applying the quantitative tools.

Data Coordination Unit (DCU)
The Data Coordination Unit (DCU) serves as the statistical and data management center for a variety of multicenter clinical trials and clinical research studies, primarily, although not exclusively, funded by the NIH. It is a unit in the DPHS. The current director is Valerie Durkalski, PhD, Professor of Biostatistics in DPHS.

Since its inception in May 2004, the DCU has managed many clinical studies, most involving multiple centers. Data and project management services are conducted using the DCU's user-friendly web-based clinical trials management system, WebDCU□. This system provides all the required tools for site coordination and data management in one efficient and easy to use system. The DCU offers study design/protocol development, central registration and randomization, data management, project management (e.g., subject study progress/calendar, automated MedWatch forms, on-line training/certification, regulatory document collection and monitoring, study drug kit inventory and shipment tracking), biostatistical support, DSMB interface, report generation, and publications. The WebDCU□ system facilitates research by maximizing the study group's productivity and efficiency. The system is efficient and reliable, and has proven to reduce the administrative responsibility at the participating centers so that more time can be spent on important scientific aspects of the studies.

Offices
The DPHS is centrally located on the main MUSC campus. The main campus is within 3 minutes walking distance of DPHS. The DCU occupies approximately 1,700 square foot of office space on the same floor as the rest of the DPHS. The building is locked during non-business hours; entry to the building during non-business hours can only be gained through the use of the swipe card entry lock. All systems used in the management and storage of clinical trials data are maintained on site at the at the limited-access offices of the DCU or the MUSC Data Center. The MUSC Data Center is approximately 4,400 sq. ft., and manned by the operations staff 24x7x365. These operators monitor all servers, environmental and notify appropriate personnel as needed. The entire data center is protected by the card access system and 24 hour security cameras are placed at each door of the third floor along with cameras at each door of the internal data center. Entry to the DCU offices can only be gained through the use of a key. The building is patrolled by security guards contracted by the building owners.

DPHS Computing Resources
DPHS computing resources include a Local Area Network (LAN) with a dedicated manager, encompassing personal computers, file servers, printer servers, and other shared peripherals. Individual computers are managed centrally for software updates and network security. In addition, DPHS has in-house resources for high performance computing, including 15 dual processor servers with 32bit 3.1GHz processors, each with 4 GB RAM processors. An 8-blade server increases the number of high performance units to 48. A grid computing initiative makes effective use of this computing infrastructure available to non-mathematicians. The scientific software licensed to the department includes MATLAB, Splus, MathCAD, SAS, Statistica, NQuery, and STATA. A variety of open source software for scientific computing is also widely used. In addition to the department web server, DPHS hosts two web servers for interfacing with applications developed in the division – the bioinformatics infrastructure of the Marine Genomics Consortium and the infrastructure for miscellaneous bioinformatics resources. To provide a stable, scalable infrastructure, the latter applications run under Linux UNIX with Apache web server configured for Secure Socket Layer with 128-bit encryption. The department has full-time staff responsible for procurement, installation, operation, and basic maintenance of hardware and software.

Center for Health Disparities Research (CHDR)
The Medical University of South Carolina (MUSC), based in Charleston, SC, established the Center for Health Disparities Research (CHDR) in 2005. Over the years, the Center has emerged into one of the leading centers of

its kind. CHDR focuses on research, training and outreach surrounding racial/ethnic, socioeconomic and rural/urban disparities in health.

South Carolina has many rural communities where chronic health problems are compounded by poor access to medical care. The state's rate for diabetes is one of the highest in the country, and our citizens face many other challenges due to heart disease, stroke, cancer and mental illness. Racial/ethnic and socioeconomic disparities in health, seen throughout the United States and the world, are also visible in Charleston, providing our team with many ways of understanding the factors that perpetuate health care disparities.

The center has built a collaborative multidisciplinary team of researchers to focus on three main priority areas including:

1) health disparities;
2) rural health; and
3) disease prevention.

Specific research activities focus on chronic diseases such as cardiovascular disease, diabetes, hypertension, cancer, connective tissue diseases and mental health disorders.

CHDR offers a number of training opportunities to grow the next generation of disparities researchers and does outreach to educate the community on finding solutions to health problems we all face.

CHDR's work is coordinated with efforts by the Charleston VA Health Equity and Rural Outreach Innovation Center (HEROIC), one of 19 VA Centers of Innovation (COIN). Dr. Leonard Egede serves as director of both CHDR and HEROIC. The synergy strengthens both initiatives as we seek to understand and eliminate health disparities and inequities through research, training and outreach.

Division of Rheumatology & Immunology
The division of Rheumatology & Immunology has a long tradition of providing outstanding care to patients of all ages who suffer from rheumatic diseases. The Division has earned an international reputation for its care and research relating to two autoimmune connective tissue diseases - Scleroderma and Lupus. Patients are seen in specialized clinics located in the Rutledge Tower at MUSC, as well as off-campus locations at MUSC Health East Cooper, MUSC Specialty Care-North and MUSC Specialty Care-West Ashley. We staff a Rheumatology Clinic at the Ralph H. Johnson VA Medical Center and provide in-patient consultation services at each of the hospitals served by MUSC - Medical University Hospital, Ashley River Tower, MUSC Children's Hospital, and the Ralph H. Johnson VA Medical Center. A wide range of services is provided, including comprehensive consultative care, infusion therapies, bone density assessments and musculoskeletal ultrasound. In Rutledge Tower, patients are seen in conjunction with the Division of Pulmonary and Critical Care and Cardiology to have pulmonary function testing and echocardiograms performed on the day of their clinic visits.

Research
The Division is engaged in both clinical and basic research. Members of the Division receive funding from the American College of Rheumatology, Arthritis Foundation, Lupus Foundation, and Lupus Clinic Trials Consortium. More than 50 articles/abstracts were authored by Division faculty last year, including papers in leading medical and scientific journals, e.g., Journal of Biological Chemistry, Arthritis & Rheumatism, and the Journal of Rheumatology. Faculty members serve on numerous federal and private scientific review committees, editorial boards, and as officers of state and national organizations. The Division was recently approved for the creation of the MUSC Inflammation and Fibrosis Research Center of Economic Excellence through the South Carolina Centers of Economic Excellence Program which focuses on clinical and translational research related to both scleroderma and lupus.
Education
The Division is proud to be training the next generation of physicians and investigators who will study and care for patients who suffer from rheumatic diseases. Faculty members actively participate in educating medical and graduate students, residents, clinical fellows and postdoctoral research fellows. The Rheumatology Fellowship Training Program, under the outstanding leadership of Dr. Faye Hant, Associate Professor, is fully accredited and comprised of 6 clinical and research fellows selected from a competitive pool of candidates. Fellows are supported in part by a NIH Training Grant (Gary Gilkeson, PI). The Rheumatology Fellowship Training Program offers fellows the opportunity to see a wide array of rheumatic disease patients in a variety of clinical settings, to

participate in clinical and basic research, and to obtain advanced training leading to a Master's Degree in Clinical Research.

Recognition
The Division of Rheumatology is honored to have been ranked 17th by U.S. News & World Report among all U.S. Rheumatology programs by other rheumatologists in their 2013 Specialty Rankings. Six members of the Division were named Best Doctors in 2012.

Multidisciplinary Clinical Research Center (MCRC)
The objective of this Multidisciplinary Clinical Research Center (MCRC) is the advancement of knowledge with respect to African Americans who have, or who are at risk of developing, systemic lupus erythematosus, systemic sclerosis, and other debilitating rheumatic diseases. The center is built on a solid framework of strong leadership in Rheumatology, Biostatistics and Health Disparities Research coupled with trust and a proven track record of recruitment of African American patients for clinical research.

Objectives of the center are to: 1) conduct and foster translational clinical research leading to improved diagnosis, management and ultimately a reduction or elimination of health disparities with respect to debilitating rheumatic diseases in African Americans; 2) focus on identifying and understanding the underlying reasons for differences in risk profiles and disease progression for African Americans; 3) provide information and education to patients and families, healthcare providers, the general public, investigators and health professionals at other academic health centers and government agencies.

The MCRC has a robust Pilot Project Program utilizing institutional funds. Institutional commitments support competitive pilot projects addressing the MCRC mission.

The MCRC consists of Cores and Funded Projects
Administrative Core
Gary Gilkeson, Director and Richard Silver, Associate Director
The Administrative Core provides leadership for the Center and support for the pilot projects. The core is responsible for the overall organization and operations of the MCRC. Key roles of the core include leveraging resources, fostering productive interactions among investigators and trainees, and enhancing collaborations with other investigators in the field.

Methodology Core
Paul Nietert, Director
The Methodology core helps the MCRC scientists with managing, analyzing, and reporting their data. They help the investigators make sure their study designs are optimal, and preform some of their own research to find new ways of handling large amounts of information from people's genes and their environments.

Patient Resource Core
James Oates, PI
The Patient Resource Core serves the Projects and research base to accelerate translational research in scleroderma and lupus to increase knowledge of pathways of risk factors and triggers for these two devastating diseases that can be modified to improve and prevent these diseases. Our community partnership increases the likelihood of translating findings to impact the community.

Project 1: Defective c- MET Signaling in African American Scleroderma Patients
Richard Silver and Galina Bogatkevich, MPIs
Interstitial lung disease (ILD) is a major complication and the leading cause of mortality in scleroderma with significantly higher morbidity and mortality rates in African American scleroderma patients. The potential pathophysiologic links between the African American race and SSc-ILD are not identified. Our goal is to fill in the gaps and identify casual factors that may account for the racial differences in SSc-ILD outcomes. These studies are the first in the field of scleroderma research to provide genetic and mechanistic evidence underpinning the known health disparities in African American SSc patients.

Project 2: Genetic and Environmental Influences on SLE and Lupus- Related Autoimmunity
Gary Gilkeson and Diane Kamen, MPIs
Systemic lupus erythematosus (SLE) is a devastating disease primarily affecting young African American women. The cause of SLE is felt to be a combination of genetics and environmental exposures. Determining these

genetic and environmental factors will provide new understanding of SLE and perhaps lead to identification of preventative strategies and/or new therapies. This project uses two unique cohorts, one from Africa and one from South Carolina, which are genetically and culturally linked yet differ significantly in environmental exposures. Studies of these cohorts will lead to new understanding of the causes of SLE.

South Carolina Clinical and Translational Research Institute (SCTR)
MUSC established the South Carolina Clinical and Translational Research Institute (SCTR) in 2006 in response to the NIH Clinical and Translational Science Award (CTSA) Program. The main thrust of the CTSA initiative is to catalyze the development of interdisciplinary research initiatives to accelerate the translation of discoveries into improved therapies and clinical practice while breaking down programmatic boundaries. MUSC has received continuous NIH funding for SCTR since 2009 with the current award extending into 2020.

SCTR has strong statewide impact with affiliate members including the University of South Carolina, Health Sciences South Carolina, Clemson University, Greenwood Genetics Center and the SC Research Authority. SCTR has implemented an extensive supportive infrastructure and developed innovative clinical and translational research tools that are available to state and regional partners and other CTSA hubs. For example, the electronic institutional Review Board (eIRB) and the well--structured Community Engaged Scholars Program with its emphasis on team science and research implementation and methods are two Institute of Medicine (IOM)--recognized examples of SCTR initiatives. SCTR's Clinical Trials Registry facilitates statewide recruitment into clinical and translational research protocols conducted by MUSC--based investigators, enhancing the diversity and representativeness of study participants. SCTR has created an outstanding platform to facilitate access and utilization to research resources, the Support Center for Clinical & Translational Science (SUCCESS), which serves as the "front door" for statewide navigation, providing access to CTSA resources for all stakeholders (http://sctr.musc.edu/success). In addition to providing direct consultation, SUCCESS partnered with Biomedical Informatics team to develop SPARC (Services, Pricing and Application for Research Centers), an online one--stop--shop catalog, request engine and work fulfillment portal for core research services and resources. SPARC is currently used by almost 20 other academic health centers. SPARC 2i is being explored as a cloud--based version to support collaborative sharing of research services and resources across CTSA

SCTR Research Nexus
The SCTR Research Nexus is a comprehensive clinical research service line for MUSC investigators that enables and enhances translational and patient-oriented research infrastructure including: a fully-equipped outpatient clinic, blood drawing station, sample preparation laboratory, specialized molecular core laboratory, and FDA-registered HCT/P (human cells, tissues and human cell and tissue based products) facility), and expert clinical research staffing (including research nurses, laboratory personnel, nutritionists, IT specialists, and a research coordinator core). The 9,200 sq. ft. facility on the 2nd floor of MUSC's Clinical Sciences Building includes 8 examination rooms, 3 procedure rooms, pulmonary function testing suite and a specialized imaging/body evaluation suite. The SCTR Research Nexus facilities provide space and support for a myriad of studies. These include but aren't limited to: investigator-initiated, federally-funded, foundation-funded, industry-initiated/industry-sponsored, and pilot studies. The overarching goal is to facilitate patient-oriented research in a cost-effective manner and help strengthen the discipline of clinical and translational science.

I. INVESTIGATOR BROCHURE
If applicable, attach the electronic version of the investigator brochure. Go to the application under "additional uploads" to attach this information.

J. APPENDIX
Attach any additional information pertinent to the application, such as surveys or questionnaires, diaries or logs, etc. Go to the application under "additional uploads" to attach this information.