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Study Protocol

Table Of Contents

Systemic Lupus Erythematosus (SLE or lupus) is a chronic autoimmune disease that is associated with increased morbidity, mortality, health care costs and decreased quality of life.[1] In the United States, African Americans have three to four times greater prevalence of SLE, risk of developing SLE at an earlier age, and SLE-related disease activity, damage, and mortality compared with Caucasians, with the highest rates experienced by African American women.[2] There is strong evidence that patient-level factors are associated with outcomes,[3] which justifies targeting them with intervention. While evidence-based self-management interventions that incorporate both social support and health education have reduced pain, improved function, and delayed disability among SLE patients,[4] African Americans and women are still disproportionately impacted by SLE.[5] Peer mentoring interventions are effective in other chronic conditions that disproportionately affect minorities, such as diabetes, HIV, and kidney disease, but there is currently no empirically tested peer mentoring intervention developed for SLE patients. 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 propose to test an innovative, manualized peer mentorship program designed to provide modeling and reinforcement by peers (mentors) to other African American women with SLE (mentees) to encourage them to engage in activities that promote disease self-management. Through a randomized, “mentored” or “support group” controlled design, we will assess the efficacy and mechanism(s) of this intervention on self-management, disease activity, and HRQOL. This study is the first of its kind in this field to test peer mentorship as an alternative strategy to improve outcomes in African American women with SLE. This could result in a model for other programs that aim to improve disease self-management, disease activity, and HRQOL in African American women suffering from chronic illness. The immediate goal of proposed work is to determine the efficacy of the program in a randomized design. The long-term goal is to disseminate this potentially cost-effective intervention in diverse clinical and community settings in an effort to improve disease outcomes in African American women with SLE and reduce morbidity and mortality in this high risk group. The following aims will be addressed:

AIM 1: Determine the efficacy of a peer mentorship intervention in African American women with SLE on disease self-management and HRQOL. Hypothesis 1: At 12 months post-randomization, mentees will report improved disease self-management and HRQOL, as measured by the Patient Activation Measure (PAM) and Lupus Quality of Life Questionnaire (LUP-QOL), compared with the social support control group.

AIM 2: Determine the impact of a peer mentorship intervention in African American women with SLE on clinical indicators of disease activity and clinical profile that indicates success of the intervention. Hypothesis 2: At 12 months post-randomization, mentees will show clinical evidence of improved disease activity measured by the patient reported Systemic Lupus Activity Questionnaire (SLAQ) and physician-collected clinical and laboratory SLE disease activity index (SLEDAI) data, compared with the social support control group.

AIM 3: Determine the cost and cost-effectiveness of a peer mentorship intervention on disease self-management, disease activity, and HRQOL, in African American women with SLE. Hypothesis 3: A peer mentorship intervention in African American women with SLE will be cost effective at improving disease self-management, disease activity, and HRQOL, as measured by quality adjusted life years (QALYS), compared with the social support control group.

An exploratory aim will be to determine the role of mediators and moderators of a peer mentorship intervention on outcomes in African American women with SLE, with the hypotheses that disease self-management will act as a mediator and depression, trust, and social support will act as moderators of the relationship between the peer mentorship intervention and disease activity and HRQOL.

The peer mentoring approach is uniquely fitted to African Americans, and this intervention has the potential to lead to health improvements for African American women with SLE that have not been attainable with other interventions. This would significantly reduce disparities and have considerable public health impact.

B1. Scientific Premise

Peer support provides a mechanism for creating a social network on a small scale that augments existing social supports and in which a person receives "support from a person who has experiential knowledge of a specific behavior or stressors and similar characteristics".[1] 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,[2-9] along with improved medication adherence and blood glucose monitoring in trials of people with diabetes.[10-16] Similarly, support group participation for women and patients with cancer and other chronic conditions has a positive impact in various areas, including quality of life, cognitive function, and fatigue.[17-32] These studies highlight the potential of peer support, and peer mentoring specifically, as a culturally sensitive means to improving health behaviors and outcomes in low income and minority groups in whom trust in the health care system may be lower than in the general population.[33-36] Previous results have shown that African American patients with SLE were more likely than white patients to have higher levels of unmet needs related to health care and information,[35,37,38] which may preclude adequate disease management[39] and contribute to persistent disparities. There is some evidence that peer mentoring has led to improvements in positive affect, sleep, social coping, and perception of bodily pain in rheumatic conditions, but there is no such peer mentoring intervention developed for SLE patients.[40,41] As a result, this study will bridge this gap in knowledge by testing a peer mentoring intervention for African American women with SLE wherein modeling and reinforcement of disease self-management skills by peers (mentors) to other African American women with SLE (mentees) will be achieved through a combination of educational and informal phone or video interactions with each other, along with the use of validated measures of patient reported outcomes and clinical indicators of disease activity to assess the efficacy of the program.

B2. Significance

This proposal addresses the mission of the National Institutes of Health (NIH) to promote and improve the health of individuals, families, and communities by proposing: 1) clinical research on health and illness that integrates the behavioral and biological sciences; 2) science to help people strengthen the quality of their lives; and 3) development of a personalized approach to maximize health and well-being for individuals. Specifically, this study will test a culturally tailored intervention that promotes better understanding and management of a chronic condition by engaging individuals as active participants in their own health, in an effort to prevent illness and promote health. This project is designed with the long term goal of improving disease self-management and quality of life, and decreasing indicators of disease activity among African American SLE patients and African American women suffering from other chronic illnesses. Addressing the public health burden of SLE. SLE (or lupus) is a chronic autoimmune disease affecting over 250,000 individuals that is marked by acute periodic flare-ups of symptoms impacting any organ system and resulting in potentially life-threatening complications.[42-44] Additional annual costs associated with SLE are estimated to be $10,000-$50,000.[45-51] Health-related quality of life (HRQOL) of patients with SLE is also significantly worse and affects all health domains at an earlier age compared to patients with other common chronic diseases and females in the general US population.[52-58]

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.[59,60] Specifically, arthritis self-management education delivered by small-group, home study, computer, and Internet modalities have demonstrated significant improvements in health distress, self-reported global health, and activity limitation,[17,61-65] but African Americans and women are still disproportionately impacted by SLE.[66-71] Persistent disparities may be due to the non-responsiveness of existing programs to the unique needs of African Americans and/or women with SLE.[35,37,59,60,72] Studies that have explored adverse outcomes in SLE patients have acknowledged the role of understanding the medical regimen, trust in the provider, and communication with providers, which are impacted by patient subjective norms, cultural, social support networks, mental health, and education. Many patients lack the education, social support, self-efficacy, and trust necessary for effective disease self-management, and these trends are more pronounced in African-Americans than Caucasians.[73-76]

Attending to unique needs within the African American community. Previous results have shown that African American patients with SLE were more likely than white patients to have higher levels of unmet needs related to health services and information.[35,37,77] These domains have included issues such as: 1) understanding the medical regimen, including considerations around depression, medication concerns (possible side effects and interactions), and physical symptoms (pain and fatigue), 2) trust in the provider, 3) communication with providers, 4) receiving adequate information from medical staff about treatment side effects, 5) having access to telephone support and advisory services, and 6) having assistance with knowing which symptoms should trigger a doctor visit.[35,37] Such deficits are compounded by findings that doctors may not be skilled in determining their needs and the barriers that lupus patients experience,[38] which may preclude adequate disease management[39] and contribute to persistent disparities.

Targeting racial disparities in SLE. In the United States, the highest lupus morbidity and mortality rates are among African American women.[43,47,60] 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.[66,70,78-80] Some have positioned elevated rates of SLE in African American women in the context of "immune cognition", and suggest that the disease, for these women, is a physical manifestation of patterns of stress, discrimination, and social disadvantage.[68,71,81-85]

Proposing peer mentoring as a solution to enhance self-management and improve outcomes. Peer mentors are usually individuals who have successfully coped with a similar condition as their mentees.[1] 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.[86] In previous studies of predominantly low income and minority populations, and those focused on rheumatologic conditions, peer mentors have been shown to help support healthy behaviors[2-16] and improvements in quality of life.[40,41] In the Peer Approaches to Lupus Self-management (PALS) intervention 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.[87,88]

Recognizing the importance of cultural tailoring to the success of behavioral intervention. Since African American women are a highly marginalized population, it is imperative to explore disease self-management approaches that are culturally acceptable, effective, and inexpensive in order to have the potential to impact chronic disease outcomes on a large scale.[36] The proposed PALS intervention incorporates culturally-relevant components that are likely to mitigate the high burden of SLE and poor outcomes of the disease in African American women. Current data show that culture-specific or culturally enhanced programs for minorities are more effective in improving health outcomes than generic programs or other control conditions.[89-91] The proposed PALS intervention has adhered to the five accepted stages of cultural adaptation:[92] information gathering was achieved through extensive literature review and ascertainment of patient and participant feedback,[59,60,93-95] preliminary design built upon lessons learned from prior behavioral interventions in the same patient population,[93,96] preliminary testing was achieved by piloting the proposed intervention in a limited sample,[87] refinement involved

incorporating participant responses and lessons learned into the final design of the proposed intervention,[97,98] and the final trial is currently being proposed.

B3. Innovation

The project is innovative because it will be the first study to test peer mentorship as an alternative strategy to improve outcomes in a high risk population with SLE. Innovative aspects of the proposed study include: 1) Developing and testing a culturally relevant intervention in an understudied disease (lupus) and underrepresented population (minority women); 2) Recruiting from a community sample of peers, making it more grassroots and easier to deploy elsewhere; 3) Accounting for financial feasibility and long-term dissemination by using peers as mentors; and 4) Using a structured approach for matching mentors to mentees to ensure effective communication and adherence to study protocol. 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 is likely to result in health improvements that have not been attainable with other interventions and serve as a sustainable solution to persistent disparities in this population. Specifically, this study is innovative is that it is culturally tailored to the unique needs of African American women with SLE, will pair mentees with mentors who are race, gender, and SES concordant to facilitate bonding and social support, and will use peer mentors who are considered competent in the management of their condition in order to provide modeling and reinforcement to participants. To ensure that the PALS project is a true translational effort that addresses the context of African American women's lives (e.g., social determinants of health), we analyzed qualitative responses of mentees that were collected as part of weekly check-ins over the course of the 12-week pilot and an end-of study semi-structured focus group to generate feedback. Qualitative inquiries and responses served as our participatory process in further refining and culturally adapting the intervention protocol.[97]

Feasibility & Preliminary Data Relevant to the Proposed Work

1. Investigative Team. This multidisciplinary team is well qualified to carry out the proposed study. Dr. Edith 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 complementary expertise. The team has worked together on both her K01 and the pilot study for this grant and this application represents a logical extension of the group's program of research geared toward improving outcomes for African American women with SLE.

2. The Balancing Lupus Experiences with Stress Strategies (BLESS) intervention (ClinicalTrials.gov Identifier: NCT01351662)Our team 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.[93,105,106]

3. Intervention to Improve Quality of life for African-AmericaN lupus patients (IQAN) (ClinicalTrials.gov Identifier: NCT01837875) We conducted 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).[96] 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. Based on feedback from subjects in the BLESS

study, the most valued aspect of the program was interaction with their peers, which informs the proposed intervention.
4. The Peer Approaches to Lupus Self-Management (PALS) Pilot Study. The PALS 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. While the PALS pilot lacked a control group, it provided a sense of general effect size and was used to design the current study.[107,108] 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, $p=0.018$). Student t tests were also conducted to compare 2-month pre- and 2-month post-intervention hospitalization charges. Mean charges per person were $24289 prior to intervention and $872 post intervention, providing very strong evidence for the intervention's potential to reduce inpatient charges post intervention.[109] 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.[87,88,97]
In summary, our preliminary studies demonstrate that in African American women with SLE, self-management education delivered in weekly sessions led to improvements in lupus self-efficacy, health distress, and depression, and 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. Additionally, using the same outcome measures across investigations will allow comparison of the impact of the current culturally tailored approach to the untailored "Better Choices, Better Health" intervention used in the BLESS study with this patient population.

B4. Approach

B4a. Theoretical Basis for Peer Mentoring

The Main Effect Model of Social Support posits that it is social relationships, and the support received from them, that are the primary drivers of improvements in both physical and mental health.99 The proposed peer mentoring intervention for African American women with SLE fits within a social support model that we hypothesize will influence this main effect by inducing downstream effects on health-related quality of life, mental well-being, and immune function, as it relates to disease activity. Within this model, we expect peer mentoring to reduce feelings of isolation and loneliness; provide culturally tailored, experiential, and evidence based education and information about accessing available health services; and promote behaviors that positively improve disease self-management, health-related quality of life, and disease activity.[86,100,101]

B4b. Study Overview. The Peer Approaches to Lupus Self-Management (PALS) study is a randomized controlled trial designed to examine whether a new, culturally tailored peer mentoring intervention improves disease self-management, indicators of disease activity, and health related quality of life (HRQOL) in African American women with systemic lupus erythematosus (SLE). African American women with active SLE will be recruited as mentees and peer mentors. We will recruit 300 mentees (150 mentored and 150 support group) and up to 60 mentors. As part of each wave, mentors (n=20) will be trained to deliver intervention content, prior to being paired with up to three mentees (n=50). The peer mentoring intervention will occur by twelve 60-minute telephone or video sessions carried out across the course of 24 weeks. In each wave, social support controls (n=50) will participate in a lupus support group

created for this project, on the same schedule as peer mentoring sessions. Both conditions will be delivered via Webex, which has several advantages for this intervention: 1) Sessions are easily accessible via phone or computer, allowing participants to choose their preferred interaction style; 2) A study coordinator can host the support groups and drop in/out for monitoring purposes; 3) There are video- or voice-call options for up to 25 participants at a time; and 4) This application ensures concordant delivery methods across both arms of the study and the ability to document the frequency that voice and video options are used to adjust for participant choices in analyses. All participants (mentees, mentors, and social support controls) will be assessed using validated measures of patient reported outcomes and clinical indicators of disease activity at baseline, mid-intervention (3 months from baseline), immediately post-intervention (6 months from baseline), and 6 months post-intervention (12 months from baseline). For each wave, outcomes for mentees randomized to the mentored group will be compared with the outcomes of mentees randomized to the support group. A booster session will be incorporated for all participants (mentored and support group) at 3 months post-intervention to encourage retention.[102]

B4c. Scientific Rigor: Assuming 3 post-randomization measurement time points, level of significance p=0.05, two-tailed comparison, correlation between pairs of measurements within participants (interclass correlation) no larger than p=0.7, AR(1) covariance structure, we estimate that 123 participants per group (total n=246) are needed to detect, with 80% power, a standardized effect size of 0.35sd with 20% inflation for attrition at 12 months. This study will apply strict principles of randomized clinical trials including randomization, blinding, careful tracking of all participants and intent-to-treat analyses to ensure robust and unbiased results.

B4d. Consideration of Relevant Biological Variables: This study considers race/ethnicity, gender, age and comorbidity as relevant biological variables. Race/ethnicity, gender, age and comorbidity will be based on self-report. The primary population of interest is self-reported black or African American women. While the burden of SLE (e.g., prevalence, severity, prognosis) is higher across a number of ethnic/racial groups in addition to African Americans, compared to Whites,[43,103,104] we have chosen to establish the efficacy of the intervention in the highest risk group (African American women). Exploratory analyses will be performed, stratified by age (<25 years, 25-34 years, 35-44 years, 45-54 years, 55-64 years, and >65 years) and number of comorbidities (0/1 vs. >2) to evaluate the differential effect of the intervention by age and number of comorbidities.

Methods for AIM 1: Determine the efficacy of a peer mentorship intervention in African American women with SLE on disease self-management and HRQOL

B4f. Study Population & Recruitment Plan

Study Population/Feasibility of Recruitment. The study population are individuals with SLE at MUSC clinics. Preliminary review of electronic medical records show that there are 1000 African American female patients with SLE who have been seen in MUSC clincis in the last year. Of these, 501 patients are enrolled in a longitudinal SLE registry at MUSC. A total of 520 African American female SLE patients (283 MUSC-wide and 237 registry) have consented to be approached for research studies. While 113 of these potential participants have participated in our prior research (thus excluding them from the current study as mentees), approximately 30 new eligible patients are expected to be seen in MUSC lupus clinics each year, bringing our recruitment pool to N=557 for mentees. Prior participants will be eligible to participate as mentors. All patients have American College of Rheumatology (ACR) criteria and disease activity information available, as well as quality of life measures available in the database. All SLE patients meet at least four components of the 1997 ACR revised criteria for SLE.[110] Our team has a successful track record of recruiting minorities into clinical trials. For example, Dr. Egede has completed 5 clinical trials with minimum of 12 months of follow up that enrolled only African Americans, the PI was able to successfully enroll 30 African American women with SLE for her BLESS study and 150 African American participants for her IQAN study within proposed recruitment periods, and for the PALS pilot, attrition was only 10%. We will use previously effective strategies for recruitment and retention including adequate patient incentives, use of minority study coordinators, token gifts at baseline visits, mailings to all participants in recognition of their personal life events, such as birthdays, births, graduations, and wedding anniversaries, certificate of completion, and a celebration at the end of each intervention wave that brings all participants together.[111,112] We are confident that these strategies will maximize recruitment and retention for the study.

Recruitment Strategy
Recruitment of Mentees
Mentees (n=300; 150 mentored, 150 support group) will be primarily recruited by a direct mailing to female African American lupus patients currently enrolled in the MUSC P30 Core Center for Clinical Research (CCCR) SLE database who have agreed to future contact as well as lupus patients from the MUSC clinics not in the registry. Flyers containing the same information contained in recruitment letters will be posted in MUSC lupus clinics and shared with local SLE support groups, other SC rheumatologists and arthritis health professionals, and local chapters of the Lupus and Arthritis Foundations for distribution to their patrons. If target recruitment is not achieved within the desired timeframe by self-selection, patients will be approached individually during clinic encounters, by phone, and/or repeated mailed/emailed or patient health record portal invitation. Patients who have indicated that they are willing to be contacted for future research in their MCRC consent forms will serve as the base for these invitations. Recruitment letters and flyers will also be shared with other academic medical institutions with eligible patient populations. Patients outside of the MUSC system who express interest will still be able to participate. They will not be required to travel to MUSC as informed consent can be obtained and questionnaires completed via REDCap, study materials can be mailed, and all other study activities can be achieved by phone.

Recruitment of Mentors
Potential peer mentors will first be invited from PALS pilot participants (mentees and mentors) (n=30), with the intention of retaining mentors to mentor multiple groups of mentees over the course of the study. It is expected that everyone would benefit from the use of experienced mentors, and using experienced mentors over time is also consistent with future real-world implementation. As needed (up to n=60, but approximately n=30 expected to be needed based on past research participation and interest), potential peer mentors who are considered competent in the management of their conditions will be identified by MUSC rheumatologists and subsequently trained by the PI. As part of the ongoing MUSC SLE database, patients are regularly flagged who providers deem competent enough to speak with the media on behalf of the patient population. We will mail out recruitment letters that will explain the study and provide participants a number to call if they are interested in participating. Participants who indicate interest in the study will be contacted by telephone to conduct a pre-screening assessment. If eligibility criteria are met, the screening/enrollment visit will be scheduled. As part of the mentor screening interview with the PI, psychosocial status will be assessed using the psychological scales of the Arthritis Impact Measurement Scales (AIMS), the Arthritis Helplessness Index (AHI), Wallston General Perceived Competence Scale, University of California at Los Angeles (UCLA) Loneliness Scale, Rosenberg Self-Esteem, Campbell Personal Competence Index, Carkhuff Communication and Discrimination Skills Inventories, and the Applied Knowledge Assessment (AKA) scale.[113] The PI will make a determination of competence, maturity, emotional stability, and verbal communication skills after overall assessment during the screening interview and training. Additional recruitment strategies will include the identification of local SLE support group members who have emerged as natural helpers, referrals from other rheumatologists and arthritis health professionals, and outreach to the local chapters of the Lupus and Arthritis Foundations by letter and telephone. Others have used these approaches successfully in multiple studies.

Study Eligibility criteria
Inclusion criteria for mentees and mentors include: 1) African American race/ethnicity and female gender; 2) clinical diagnosis of SLE from a physician, according to ACR revised criteria for SLE.[110]; and 3) 18 years of age or older. Additional inclusion criteria for mentors include: 1) disease duration > 2 years; 2) able to attend scheduled training sessions; and 3) willing to provide one-on-one support to up to three African American women with SLE. Mentees who participated in the pilot will be ineligible to participate in this study as a mentee, but could participate as a mentor if they meet other eligibility criteria.

B4g. Overview of the Peer Mentoring Intervention
Peer Mentoring Intervention Elements
Mentor Training: The principal roles of the peer mentors are to: 1) provide information about SLE, SLE-related behaviors, thoughts, and feelings, and the nature of recommended treatments; 2) provide social

support to alleviate the mentee's sense of social isolation; 3) enhance and reinforce the mentee's sense of self-efficacy to manage their condition; and 4) encourage the mentee to participate actively in the recommended self-management skills building therapy. Mentors will be trained in conversational strategies to help them meet the objectives without being overly directive and will be instructed not to give clinical advice.[114] Upon enrollment, peer mentors will receive 12 hours of training, broken into two 6-hour blocks, prior to working with mentees.[114] Mentors will be given a written manual presenting all the material in detail for their ongoing reference. The training manual was developed in collaboration with social work leadership from Hospital for Special Surgery's LupusLine® Program. The program, led by the Department of Social Work Programs, is a free telephone counseling service staffed by trained volunteers who have SLE or are close family or friends of people living with lupus.[113,115] Training will will include the following:
1) Review of slide presentation and rationale for learning self-management, as well as the contribution of biological, psychological, and social factors to the SLE experience;
2) demonstration and practice of some basic skills to use in working with the mentee;
3) review of the manual; outline of the format and required elements for each call;
4) participation in role-playing exercises in pairs to learn ways of presenting didactic information, supporting positive statements, and responding to questions posed by the mentee;
5) participation in question development and topic starter exercises;
6) participation in troubleshooting exercises to suggest ways of addressing particular problems; and
7) review of call formats, reporting requirements and detailed discussion of emergency situation procedures.

Mentee pairing: After enrollment and completion of baseline assessments, mentees will be matched with peer mentors based on as many specific shared concerns of their experiences as possible. Potential matching areas include disease symptoms, parenting, work-related concerns, similarity of life stage (including age)]41] and demographics (including area of residence), similarity of personality characteristics, and peer mentor availability, and will be assessed as part of the screening process.

Overview and Description of the PALS Intervention:
Recruitment and enrollment: This will occur in 3 waves. Within each wave, each mentor will be assigned all of their mentees at one time to ensure that intervention activities occur within the same 12-month period. As mentor:mentee quads (1 mentor, 3 mentees) are identified, they will attend an introductory session together, during which the mentoring process will be discussed, including time commitment, roles, responsibilities, benefits, and ground rules, and mentees and peer mentors will have the opportunity to ask questions and make informed decisions about their ability to fully participate in the intervention. If face-to-face meetings are not possible for all members of the quad, skype or another form of video meeting will be attempted. Mentees will be informed that she will be dropped from the study if she misses three consecutive or four of the 12 total educational sessions for non-emergency reasons; peer mentors will only be permitted to miss three educational sessions in total. Any missed educational content on the part of the mentee or mentor will be added to subsequent sessions and emphasized in booster sessions.
Description of The PALS Program: The program will consist of 12 sessions of peer mentoring that will include one standard educational session by telephone or video for approximately 60 minutes every 2 weeks. Additional interaction will be discouraged, but mentees and mentors will be asked to report any additional social interaction should it occur. The bi-weekly educational session will be generally structured in three parts: introduction, structured education, and problem solving. 60-minute calls are necessary for the delivery of educational content and mentors and mentees to be able to discuss their own experiences and potential solutions. Bi-eekly content has been adapted from the six modules of the Chronic Disease Self-Management Program (CDMP), Arthritis Self-Management Program (ASMP), and Systemic Lupus Erythematosus Self-Help (SLESH) Course,[61,116] and further tailored to African American women with six added sessions based on cultural issues reported as important to African Americans in earlier research conducted by the PI[93,117] and documented unmet needs in the African American SLE patient community.[94,95]
Tailoring of the PALS intervention: To address unmet needs around understanding the medical regimen, including considerations around depression, medication concerns, and physical symptoms, culturally relevant sessions on 'Complications' and 'Self-monitoring' were developed. In response to unmet needs

around trust in the provider, communication with providers, and receiving adequate information from medical staff about treatment side effects, sessions on 'Coping' and 'Trust' were developed. Lastly, unmet needs around having access to telephone support and advisory services and having assistance with knowing which symptoms should trigger a doctor visit[35,37,77] are addressed by the PALS study design (i.e., telephone/video delivery of intervention) and sessions devoted to less frequently discussed topics of 'Body image' and 'Sexuality/sexual health'. The PALS pilot was then used for initial refinement of the intervention protocol. We analyzed qualitative responses that were collected as part of weekly mentee check-ins, mentor logs, and the end-of study focus group. Themes that emerged included: a) interpersonal, familial and romantic relationships; b) individual experiences of living with SLE; and c) physician-patient relationships. Additional themes emphasized how the intervention worked bi-directionally wherein both mentors and mentees were empowered toward greater disease self-efficacy. We 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 being able to discuss topics that they felt were often marginalized by healthcare professionals, such as sexuality; and 3) the intervention encouraged reciprocity. Such dynamic discussions served as a participative approach to determining which components of the intervention were most useful to participants. Based on observed themes, unique concerns of our study population have been built into the proposed intervention. Specifically, the importance of faith and spirituality in coping with their disease, the impact of chronic pain on their interpersonal, familial, and romantic relationships, the need for more sensitivity in interactions with medical staff, and the importance of support and relationship building in mentee-mentor interactions have been incorporated into session 4: effective communication, session 10: self-monitoring, and session 11: sexuality, of the PALS implementation plan and training protocols, to ensure that culture-bound myths and concerns about SLE are addressed in this cultural group.[97]

Control Intervention (Support Group): Mentees randomized to the social support control group will be enrolled in a lupus support group designed specifically for this project. Unlike traditional support group meeting formats that are open to all lupus patients, family members, friends and supporters; advertised publicly; implemented by a trained facilitator; and generally include a specific discussion topic or an informative presentation, the PALS-specific support group will be limited to PALS control participants, be moderated by a PALS study coordinator who will not provide any information or discussion topics, and will simply provide a meeting session via WebEx for social support control participants to interact on a bi-weekly basis.

Treatment Fidelity: At the onset of the study, peer mentors will receive extensive training. Dr. Oates will provide training in pathophysiology, clinical management, and effective strategies of lifestyle management in SLE. Ms. Rose will provide primary training on peer-mentoring and monitor counseling skills using audit and feedback. Dr. Williams will provide training on social support, telephone engagement and follow up and conflict resolution.[111,112] In addition, Dr. Williams will provide ongoing oversight of peer mentoring sessions. Training will consist of two full days of information and role-playing and then one day booster sessions in years 2-5 to minimize drift in peer mentoring skills.[102] After initial training, peer mentors will continue to meet with the PI bi-weekly to identify challenges and reinforce the guidelines for peer mentors.[114] Mentors will be required to submit logs of the number of calls made, number of hours spent with mentees, and content covered during that two-week period, in order to be compensated. To assess the frequency and duration of calls, other interactions with their mentor and whether specific content has been covered, mentees will receive a link to a brief REDCap survey by email and/or text message every two weeks. Additionally, a subset of sessions will be recorded to allow direct evaluation of the contents of interactions. Self-report assessments will be used to track the effectiveness of the intervention. Fidelity will be considered acceptable if: 1) a given participant completes at least 9 of 12 sessions (peer mentoring or support group) or receives corresponding content and achieves at least 9 hours of interaction; and 2) all assessments (baseline, mid-intervention, and post-intervention) are completed within 1 week of distribution.

Data Collection Strategy

Data Collection Process/Schedule: Fourteen trained peer mentors will deliver the intervention in each wave and one full-time study coordinator (SC) will conduct screening, consent, enrollment procedures, and support group moderation. The primary method of data collection will be face to face interview. Mentees will be assessed at baseline, mid-intervention (3 months from baseline), immediately post-intervention (6 months from baseline), and 6 months post-intervention (12 months from baseline). Physical examination and laboratory evaluation will be achieved by in-person clinic visit when recent SLEDAI scores are not available in the database record of a given participant. Social support control participants will complete assessments on the same schedule as mentored participants. Given evidence that peer support may be just as beneficial to the supporters as it is to the person being supported,[118,119] mentors will be assessed on the same schedule as mentored and control participants, using the same tools.

Primary Outcomes for Aim 1 will include:
Quality of Life: The LUP-QOL incorporates the Medical Outcomes Study (MOS) Short Form 36 Health Survey (SF-36) and the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F), which are reliable and valid instruments that are frequently used in quality of life studies of persons with lupus.[120,121] Self-Management: The Patient Activation Measure (PAM)[122,123] assesses an individual's knowledge, skill, and confidence for managing their health and healthcare. Individuals who measure high on this assessment typically understand the importance of taking a pro-active role in managing their health and have the skills and confidence to do so.

Secondary Outcomes for Aim 1 will include:
Treatment Credibility: To assess for differences in outcome expectancy, a modified treatment credibility scale developed by Borkovec and Nau (1972) will be used. Four of the questions will be used for this study, with 10-point Likert scales. These include questions regarding how logical the treatment seems, how confident participants are about treatment, and their expectancy of success. Satisfaction with Care: Satisfaction with Care will be measured with a previously validated general scale to measure satisfaction/dissatisfaction with health care. The 2-item scale ranges from 1 (Strongly Agree) to 5 (Strongly Disagree).

Covariates for all three aims will include:
Demographics: Previously validated items from the 2002 National Health Interview Survey [NCHS 2004] will be used to capture age, marital status, education, household income, and health insurance. The 28-item Brief Index of Lupus Damage (BILD) was developed as a patient-reported measurement of lupus disease damage designed to quantify cumulative organ damage due to SLE regardless of attribution. The self-administered version of the BILD has been validated in a predominantly African American independent community-based cohort of SLE patients from the Southeastern US.[67] Coping: Coping will be assessed by the Arthritis Self-Efficacy Scale pain and other symptoms sub-scale,[124] which consists of 11 items designed to measure confidence in one's ability to manage the pain, fatigue, frustration, and other aspects of disease.[64] Depression: The PHQ-9 is a brief questionnaire that scores each of the 9 DSM-IV criteria for depression as "0" (not at all) to "3" (nearly every day). PHQ-9 score > or =10 have a sensitivity of 88% and a specificity of 88% for major depression.[125] We will use a modified version of the PHQ-9 that does not include the last question about suicidality, making it the PHQ-8. Anxiety: General Anxiety Disorder (GAD) will be assessed using the 8-item anxiety scale (GAD-8). This is a valid and efficient tool for screening for GAD and assessing its severity in clinical practice and research.[126] Perceived Stress: The perceived stress scale (PSS) is a 4-item scale that assesses the degree to which the respondent finds situations stressful.[127] Responses range from "0" (never) to "4" (very often) and questions ask about the frequency of feelings related to events in the previous month. The Cronbach alpha value is 0.69 and scores are highly correlated with stress, depression and anxiety. Chew Health Literacy Screening: The Chew Health Literacy Screening Survey[128] is a 3-item instrument designed to rapidly screen patients for potential health literacy problems. To test whether unique needs are better met in the group receiving the peer mentorship intervention compared to the group receiving social support, this instrument will be adapted to include questions about understanding the medical regimen, including considerations around depression, medication concerns (possible side effects and interactions), and physical symptoms (pain and fatigue), and knowing which symptoms should trigger a doctor visit.[35,37,77] Measures of Social Support, Trust, and Patient Centered Care will be administered to test

whether unmet needs around trust in the provider, communication with providers, receiving adequate information from medical staff about treatment side effects, and having access to telephone support and advisory services are better met in the group receiving the peer mentorship intervention compared to the group receiving social support. Social Support: The Medical Outcomes Study (MOS) Social Support Survey[129] will be used to measure social support. The total scale (d=0.97) and subscales (d=0.91 to 0.96) have high internal consistency, good criterion and discriminant validity, and one-year test-retest reliability (0.72 to 0.76). Trust: Trust will be measured using The 17-item Multidimensional Trust in Health Care Systems Scale (MTHCSS).[130] Items are scored on a 5-point Likert scale with scores ranging from 5 (strongly agree) to 1 (strongly disagree). The higher scores represent greater trust in the healthcare systems. Patient Centered Care: Patient-Centered Care will be measured using the Modified Picker Survey. It is a 7-item scale that measures patients' experience with the physician. Scores range from 1 (Always) to 4 (Never).

Methods for AIM 2: Determine the impact of a peer mentorship intervention in African American women with SLE on clinical indicators of disease activity and clinical profile that indicates success of the intervention

Disease activity will be assessed using both physician assessment and patient-reported outcome measure. The Systemic Lupus Activity Questionnaire (SLAQ)[131] asks a single Patient Global Assessment (PGA) question about presence and severity of lupus activity over the past month, questions on 24 specific symptoms of disease activity and a single Numerical Rating Scale (NRS) asking the patient to rate disease activity on a scale of 0-10 over the past three months. Use of immunomodulatory drugs and prednisone (total dose and tapers) will also be assessed. For physician assessment of disease activity, the Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) has been individually validated and found reliable in clinical trials. SLEDAI scores are routinely collected as part of regular visits and clinical, demographic, genetic, disease activity/damage, genetic, and laboratory data are stored in the longitudinal web-based SLE database at MUSC as part of NIH-funded P60 and P30 grants (see Oates biosketch). All clinicians recording SLEDAI scores are trained in this assessment with annual refresher courses as part of their participation in industry-sponsored clinical trials. SLEDAI scores for each participant will be extracted from the database when available for dates within the same month as baseline, mid-intervention, and post-intervention data collection points. When scores are not available in the database, the participant will be scheduled for a clinic visit that will include vitals, blood collection, and labs to ascertain SLEDAI score. Clinic visits will take place within the South Carolina Clinical & Translational Research Institute (SCTR) Research Center (Research Nexus) at MUSC. The SC will coordinate questionnaire administration, clinic visits for SLEDAI ascertainment, and data entry. Physical examination and laboratory evaluation will be achieved by in-person clinic visit when recent SLEDAI scores are not available in the database record of a given participant. Social support control participants and mentors will complete assessments on the same schedule as mentored participants. The SLEDAI is a multicomponent, 24 question survey of clinical and laboratory signs and symptosm used as a representation of a phsyician's assesment of a patient's disease activity over the last 30 days (see Appendix). Items are weighted based on their severity ranging from a multiplier of 8 to no multiplier (i.e. 1). The maximum 'score' for the test is 105.[132] Validated clinically meaningful changes in SLEDAI scores are -6 for improvements and +8 for worsening disease activity.[133]

Methods for AIM 3: Determine the cost and cost-effectiveness of a peer mentorship intervention on disease self-management, disease activity, and HRQOL, in African American women with SLE

Resource use and cost information will be collected to inform a well-designed economic study of the cost-effectiveness of the use of peer mentors for SLE patients in the acute care setting. Cost of the intervention will include all personnel, equipment, supply and space cost associated with training and use of peer mentors, in real time dollar values. MUSC inpatient and outpatient costs of healthcare utilization of any MUSC services will be collected from MUSC administrative billing data based on ICD9/10 codes, Medicare Diagnosis Related Group (MSDRG), and CPT codes related to lupus to estimate distributions of cost for the medical care resources used. 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. Questionnaire responses will be used to ascertain care resources that patients use during the study period from other hospitals or entities who are not part of the MUSC record system.
Healthcare Utilization: Stanford Patient Education Research Center Questionnaires[134,135] assessing medical outcomes such as hospital visits will be adapted to include questions related to use of other services, such as ER visits, other medical care resources of importance to patients, economic and financial barriers to use of care outside the hospital setting including loss of time at work/productivity, and any issues related to recidivism of patients once they no longer have mentor support.[136-138]

Power and Sample Size Justification: The sample size calculation and power analyses are based on the primary outcome of change in HRQOL between baseline and 12 months post intervention. The minimum sample size was based on detecting a clinically meaningful difference of 0.35 standard deviation units (medium effect) based on prior studies.[87,93,139-143] Essentially, this is equivalent to testing the interaction between time and group. Assuming 3 measurement time points, level of significance p=0.05, two-tailed comparison, correlation between pairs of measurements within participants (interclass correlation) no larger than p=0.6, compound symmetry covariance structure, we estimate that 123 participants per group (total n=246) are needed to detect, with 80% power, a standardized effect size of at least 0.35sd. This sample size includes a 20% inflation for attrition at 12 months. This effect size is robust enough to provide sufficient power for the outcomes listed under aims 1 and 2 and is consistent with data from our pilot study of 20 mentees and 7 mentors (see preliminary data). The pre-post differences in the outcomes (such as overall social support, positive social interaction, tangible support, vitality, emotional support, social functioning, general health, coping, etc), ranged from 0.35 to 0.88 standard deviation units. Although these calculations account for within patient clustering through the intera-class correlation mentioned above, clustering within mentors and mentees are assumed to have minimal intra-class correlation based on pilot data, especially since the cluster sizes would be at most 3 at a given wave. However, a multi-level model will be used in the analysis to verify this. Since the effect size planned is conservative, if the clustering leads to higher intra-class correlation, we would still be able to detect meaningful differences. We will also consider including mentor as a fixed effect in the model.

Randomization Procedure: Participants recruited for the mentored or control (support group) portion of the study will be randomized using a block randomization procedure to assure equal sample sizes in the mentored and control groups. Using a block size of 3, participants will be assigned to the appropriate treatment condition as they enroll in the study until the block is completed. Then the following 3 participants will be assigned based on the next block.[144] Once a patient is randomized and attends the first session, she will be entered into the study and included in the intent-to-treat analysis plan. Subjects will remain blinded to group allocation until after the completion of baseline assessment. The only members of the research team who will be aware of randomization assignment will be the Research Coordinator, and the statistical analyst in charge of randomization. Randomization will occur at the patient level. As such, we will take the following steps to minimize contamination between the two arms of the study: 1) patients in the intervention and control arms will be instructed not to share intervention materials with family members, friends, or other clinic patients; 2) patients will be given instructions not to disclose their treatment assignment to their assessment interviewers.

Data Management: Data will be captured via REDCap (a free, secure, web-based application) and overseen by a data management and analysis team comprising statisticians at MUSC. Data will be collected electronically in password-encrypted files. A part-time masters-level statistician will be responsible for data management. Data will be reviewed on a bimonthly basis and issues will be communicated to the project coordinators. In particular, outlying and inconsistent data values, as well as missing data, will be the targets of the data quality review.

Overview of Statistical Analysis Plan
Univariate descriptive statistics and frequency distributions will be calculated as appropriate for all variables for the total sample. Descriptive analysis will be presented as percentages (with 95% confidence intervals [95% CI]) for categorical variables, and either means (±Standard deviation) with 95%

CI or medians (with interquartile range) for continuous and ordinal variables on the biological indicators of disease activity, as appropriate, based on distributional assumptions. These analyses will provide descriptors of the respective parameters in the study population and will also be used to identify departures from distributional assumptions for proposed procedures. If departures are identified, appropriate transformations of data will be applied, or alternative analysis procedures (e.g., semi-parametric or nonparametric) will be used.

AIM 1: Determine the efficacy of a peer mentorship intervention in African American women with SLE on disease self-management and HRQOL. Analyses for Aim 1 will focus on estimation of efficacy as determined by: (a) change in quality of life; and (b) change in self-management. 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) with two-sided p-vales denoting statistical significance to provide an indication of the presence of a clinically important treatment effect.[145,146] A p-value of 0.05 will be considered to be statistically significant. After studying the distributions of baseline characteristics, we will use a generalized linear mixed model regression model to determine if the intervention will produce a greater change in the main outcomes from baseline. This model will include time, treatment (along with their interaction), and covariates (including the amount of intervention received, demographic factors, medications, coping, depression, stress, anxiety, health literacy, trust, and social support) as fixed-effects. Using the amount of intervention, which is measured as an aggregate number of sessions completed or hours of interaction as a covariate would allow us to study the dose response. In the generalized linear mixed model (GLMM), we will use different link functions depending on the assumed distribution of the response variable. For binary outcomes, we will use logit link and for count outcomes we will use log link under a poisson or negative binomial distribution. For example, for the a given quality of life variable, HRQOL measured at baseline, month 3 and month 6, we will include intervention group, time, and time X intervention as the primary independent variables in the basic (unadjusted) model, and covariates that are not balanced at randomization (or a propensity score based on these covariates) will be added in the subsequent (adjusted) model to adjust for the possible confounding effect of these variables. Unadjusted and covariate-adjusted least squares means for each outcome variable will be compared at the primary time point (month 12) and at intermediate secondary time point (month 6) using appropriate model contrasts and the Tukey-Kramer adjustment for multiple comparisons for the secondary time points. These contrast comparisons, along with corresponding 95% CI, will provide estimates of the difference in outcome means (effect sizes) for the hypothesized comparisons.

AIM 2: Determine the impact of a peer mentorship intervention in African American women with SLE on clinical indicators of disease activity and clinical profile that indicates success of the intervention. Analyses for Aim 2 will focus on estimation of efficacy as determined by: change in disease activity of ≥4 point reduction from baseline in SLEDAI score, in concordance with the accepted SLE Responder Index (SRI).[147] For comparative statistical assessments, the two groups will be compared using a generalized linear mixed models (GLMM) approach.[148] This approach allows for measurement of participants at different time points, missing data under the assumption of missing at random (MAR), and can also account for the effect of correlated longitudinal measurements within participants. In addition, GLMM accommodates a wide range of distributional assumptions such as dichotomous (e.g. binomial), count (e.g. Poisson), continuous (e.g. Gaussian), and categorical or ordinal outcomes. Additionally, outcomes that are measured longitudinally (at 6 and 12 months) will have intervention group, time, and time-by-intervention group as primary independent variables in the model. Additional adjustment co-variables will be added to the model in a second set of analyses, when indicated. The magnitude of between intervention differences in outcome variables (effect sizes) at each time point will be estimated using appropriate contrasts in the corresponding GLMM models. We will then perform a responder analysis to develop a profile of the clinical and laboratory characteristics that predict success of the intervention. For this, a multivariate regression logistic regression model where the outcome is success (/failure) and the difference in the clinical (SLEDAI components) levels over time are independent variables. We will use model selection approaches such as the all subsets selection, to identify the important clinical and laboratory features in the presence of others. As much as the data allows, we will also consider interactions of the SLEDAI components. As an alternative to logistic regression, we will also consider other approaches such as the CART, or logic forest to efficiently identify the clinical and laboratory characteristics that predict intervention success.

Secondary analyses of process measures: Important process measures will include recruitment, session attendance/dropout 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 peer mentoring intervention using a likert-type satisfaction scale and will determine the proportions (along with CI) within the categories. For continuous process measures (e.g. treatment credibility, treatment adherence, peer mentoring phone sessions and attrition), frequency distributions and the median and mean responses (with 95% CIs) will be obtained.

Exploratory analyses to determine the role of mediators and moderators on outcomes and obtain estimates of the effect of the intervention on mentors: Analysis for exploratory aims will focus on change scores over time for potential mediator and moderator variables related to identified unmet needs unique to African American women with SLE, including: (a) Anxiety; (b) Depression; (c) Stress; (d) Coping; (e) Health Literacy; (f) Trust; (g) Social Support; and (h) Patient centered care. Differences between baseline and post-baseline measurements will be tested with the Wald test in the GLMM model. As described for Aim 1, estimates of effect sizes for the outcome variables will be obtained via 95% confidence intervals (CI) to provide an indication of the presence of a clinically important treatment effect. Individual treatment change scores (pre-post) will be estimated via 95% CI (adjusting for clustering).[145,146] Since the intervention is designed to improve outcomes in mentees, we will not have power to test the efficacy of the intervention in the mentors, but will explore the effect of the intervention on the mentors using the same analytical methods.

Missing data: We will handle missing data using several techniques including multiple imputation and maximum likelihood,[149] and latent class based multiple imputation.[150] Missing data mechanisms will be examined using both univariate and multivariate methods. We will check for missing at random (MAR) by creating a missing indicator for each missing variable and study the predictors of missingness using logistic regression. If any of the fully observed covariates or outcomes become significant in the missing data model then we will use methods for MAR if we do not have any reason to believe that the missing data mechanism is not at random.

Mid-point Analyses for the protection of participants: In an effort to protect both mentors and mentees from potential deleterious effects of mentoring, a mid-point (interim) analysis will be undertaken to assess safety using 3-month post-intervention data. If mentored participants have worsened beyond a threshold, we will stop the trial for ethical concerns. For instance, if the lower confidence limits based on 95% confidence interval at the midpoint, for any one of the variables, namely depression, anxiety, and/or disease activity, is larger than 50% compared with their baseline measure, the trial will be terminated. Similarly, mentors will be monitored for depression, anxiety, and disease activity and if a worsening trajectory is observed at mid-point analyses, they will be removed from the study.

AIM 3: Determine the cost and cost-effectiveness of a peer mentorship intervention on disease self-management, disease activity, and HRQOL, in African American women with SLE.
The cost of the intervention will be compared to the outcomes of the intervention 12 months post baseline. In order to compare with previous lupus studies,[151,152] Quality adjusted life years (QALYS) will be calculated for intervention and control groups based on the SF36 outcome which will be measured 12 months post baseline. The calculation will be based on an established peer reviewed method.[153] Measuring QALYS gained relative to cost of the intervention is the preferred outcome method for the American College of Physicians (ACP).[154]

Using QALYs, the incremental cost-effectiveness ratio (ICR) can be calculated as: (QALYintervention-QALYcontrol)/(Costintervention-CostControl). The ICR can then be compared with the ICRs for previous lupus interventions. We will take the perspective of the provider, insurer and patient. All three are affected in the hospitalization charges since insurers pay part and patients will pay part of the charges. In addition to the main cost-effectiveness outcome of QALY and the ICR, costs of the

intervention can be compared with any changes in MUSC health services utilization costs for emergency department, inpatient and outpatient care for the intervention relative to the control group. In addition to a comparison of intervention cost with average difference between MUSC costs for intervention and control group 12 months post baseline, generalized linear cost models can be estimated to examine the association of the treatment with MUSC health services costs while adjusting for patient demographics (age, gender, race/ethnicity, co-morbidities) and clinical outcomes. MUSC does not provide cost information, only charges. In addition we will estimate the impact on work loss and income by estimating the changes in days lost to illness and income based on values provided by participants. We will use the year for which the hospital charge and income data is reported and adjust for inflation as appropriate using the US Department of Labor Consumer Price Index. Inpatient and outpatient MUSC costs will be compared separately and together between the control and intervention groups. Bootstrapping methods will be used to conduct sensitivity analyses for all cost models. Sensitivity analysis will be performed by estimating a separate MUSC health services cost model while adjusting for each clinical outcome to insure robust results regarding the marginal effect of the treatment on MUSC health services costs. Park tests will be conducted to determine the best fit for the cost data in specifying the generalized linear model. In the event of many zero values, a two-part model will be used to first examine the association of the treatment with the likelihood of any MUSC costs and then the conditional generalized linear cost model, conditional on having non zero MUSC cost value for the patient. The ICR will be reported as a single ratio with no uncertainty attached to it. Therefore, standard statistical characteristics such as confidence intervals or hypothesis test to compare it to an a priori ICR from another study are not applicable. We will calculate the ICR and a clinically relevant interpretation of the outcome will be p Human Subjects Involvement and Characteristics. The Peer Approaches to Lupus Self-Management (PALS) study is a randomized controlled trial designed to examine whether a new, culturally tailored peer mentoring intervention improves disease self-management, indicators of disease activity, and health related quality of life (HRQOL) in African American women with systemic lupus erythematosus (SLE). African American women with active SLE will be recruited as mentees and peer mentors who are considered competent in the management of their condition will be identified and recruited to provide modeling and reinforcement to participants. We will recruit mentees for 300 observations (150 mentored and 150 support group) and up to 60 mentors. Mentees and mentors will be primarily recruited from the longitudinal web-based SLE database at the Medical University of South Carolina (MUSC) in three cohorts. As part of each cohort, mentors (n=20) will be trained to deliver intervention content, prior to being paired with up to three mentees (n=50). The peer mentoring intervention will occur by twelve 60-minute telephone or video sessions carried out across the course of 24 weeks. In each cohort, social support controls (n=50) will participate in a lupus support group created for this project, on the same schedule as peer mentoring sessions. All participants (mentees, mentors, and social support controls) will be assessed using validated measures of patient reported outcomes and biological indicators of disease activity at baseline, mid-intervention (3 months from baseline), immediately post-intervention (6 months from baseline), and 6 months post-intervention (12 months from baseline). For each cohort, outcomes for mentees randomized to the mentored group will be compared with the outcomes of mentees randomized to the social support control group. A booster session will be incorporated for mentored participants at 3 months post-intervention to encourage retention.

Inclusion criteria FOR MENTEES include: 1) African American race/ethnicity and female gender; 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, interviews); 5) able to commit to duration of study (12 months); and 6) able to communicate in English. Exclusion criteria FOR MENTEES include: 1) cognitive impairment; 2) active alcohol or drug abuse/dependency; 3) acute decompensation of chronic conditions precluding participation; 4) conditions that preclude participation in assessments (e.g. blindness or deafness); 5) terminal illness or life expectancy less than 18 months as evaluated by physician; and 6) current enrollment in an interventional study or trial that could affect quality of life outcomes and/or participation in one of the PI's prior behavioral trials.

Inclusion criteria FOR MENTORS include: 1) African American race/ethnicity and female gender; 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, interviews, observation, activity logs); 5) able to commit to duration of study (12 months); 6) able to communicate in English; 7) disease duration > 2 years; 8) able to attend scheduled training sessions; 9) willing to provide one-on-one support to up to three African American women with SLE; and 10) PI determination of competence, maturity, emotional stability, and verbal communication skills after overall assessment during screening interview and training. Exclusion criteria FOR MENTORS include: 1) cognitive impairment; 2) active alcohol or drug abuse/dependency; 3) acute decompensation of chronic conditions precluding participation; 4) conditions that preclude participation in assessments (e.g. blindness or deafness); and 5) terminal illness or life expectancy less than 18 months as evaluated by physician. rovided similarly to other studies in the literature.[155,156]

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 peer mentorship 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.

Research Material & Data: Sources of research material include medical records, research questionnaires, and blood specimens. The data will be obtained for research purposes.

2. Linkages to Subjects: Participants 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:

A. Personnel: A full-time research coordinator (RC) and part-time data coordinator (DC) will be responsible for consent, enrollment and data collection.

B. Data Collection Schedule: At the baseline visit, the RC will give detailed explanation of the study, the reimbursement schedule, and obtain consent. Participants will provide a blood sample, if necessary, and complete a questionnaire that captures demographics, health literacy, coping, disease activity, disease self-management, anxiety, depression, perceived stress, social support, trust, patient centered care, perceived control, perceived discrimination, spirituality, and quality of life. The RC 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 months (questionnaire only) and 12 months (questionnaire and blood collection). As much as possible, research visits will be scheduled on the same day as their clinic visit. Mentors and mentees will be on the same schedule of data collection, regardless of whether a mentor has assigned mentees after their enrollment.

Potential risks to mentees and mentors include: 1) discomfort, bruising, or scarring from venipuncture, 2) possible violation of the patient's privacy, 3) discomfort with questions on the research questionnaire, and 4) psychological distress. Additional risks to mentors specifically include: 1) discomfort with interactions with mentees and 2) feeling overwhelmed. 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. To further ensure confidentiality, participants will be provided

with a basic phone and calling/texting plan for the duration of the study for mentoring interactions so that personal phones are not used.

Recruitment and Informed Consent. All African American lupus patients who indicate willingness to participate and meet the inclusion criteria of the study will be invited to participate in data collection. Informed consent will be sought from each participant for participation in intervention and data collection activities. Participants will be encouraged to ask any questions they have regarding the procedures. There will be no coercion to participate or prejudice against those who choose not to take part in the study. We will submit an application to the Medical University of South Carolina Institutional Review Board for approval of study procedures and the informed consent protocol. Study activities will not take place prior to IRB approval.

After obtaining approval from the IRB, we will obtain a list of potential mentors from MUSC rheumatologists and the full list of female African American SLE patients enrolled in the web-based SLE database who have consented to future contact to be contacted as mentees. We will mail out recruitment letters that will explain the study and provide participants a number to call if they are interested in participating. Participants who call and indicate interest in the study will be contacted by telephone to conduct a pre-screening assessment. If eligibility criteria are met the screening/enrollment visit will be scheduled. Additional recruitment strategies will include invitations to other academic medical centers with eligible patient populations, the identification of local SLE support group members who have emerged as natural helpers, referrals from other rheumatologists and arthritis health professionals, and outreach to the local chapters of the Lupus and Arthritis Foundations by letter and telephone.

Written informed consent to obtain and use clinical data and specimens will be requested by the research staff, using paper or electronic (eConsent via REDCap survey format on computer or tablet) consents. If the participant is seen in person, the default will be paper consents. The participant will be given the opportunity to read the consent before the study coordinator goes over it with them. The study coordinator will introduce him or herself to the potential participant during the course of a normal outpatient clinic visit, describe the study in further detail including the possible discomforts of the procedure(s), the purposes for which the samples are being taken, and that s/he will not personally benefit from the results. Any questions that the patient might have will be answered by the study staff as appropriate. This process will be conducted in a closed room within the clinic to ensure a proper, private environment. If they agree to participate, the study coordinator will ask the patient to sign the standard participation consent and a HIPAA form.

Once the participant has the informed consent open on a computer or tablet, they are able to scroll through (using mouse or finger) and read the document in its entirety, just as they would an article on a website. The study coordinator will guide the participant through the consent, asking open-ended questions to assess their comprehension of the study procedures. As the participant finishes reading sections of the document that require initialing or signature to provide consent for specific procedures, they are given the ability to do so by clicking on a link stating “add signature.” Each of these links provides verbiage identical to the paper consent form indicating the procedures for which they are being consented. These initials and signatures are completed by using their finger (tablet) or the mouse (computer) and accepting the changes by clicking “save signature.” Only the portions of the document that require the initials or signature of the participant will be provided to the participant, ensuring that they will not sign, initial, or date the improper portion of the document (e.g. – signing on the line for the person obtaining consent). The study coordinator will then be allowed to print their name, sign and date the form independent of the participant. The “submit” button is then pressed at the bottom of the screen by the study coordinator which then automatically opens the HIPAA document for the same review and signature/initialing process as above. Just as for paper copy consenting above, the eConsent process will be conducted in a closed room within the clinic to ensure a proper, private environment, and the study coordinator will conduct the eConsent process over the phone with the participant. In this event, the participant will be sent an electronic copy via email before the consent call, so that they can read the documents before the researcher goes over it. All participants will receive copies of the appropriate consent forms and HIPAA notice.

Given the complexity of SLE and the overall study goal to provide modeling and reinforcement by peers to other African American women with lupus (mentees) to encourage mentees to engage in activities that promote the learning of disease self-management skills and support the mentees' practice of these learned skills, every attempt will be made to ensure that the study/mentorship does not negatively impact the mentee. To address this potential concern the following approach will be implemented:

1. Upon enrollment, peer mentors will receive training, prior to working with mentees.
2. Mentors will be given a written manual presenting all the material in detail for their ongoing reference.
3. Mentors 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, peer mentors will continue to meet with the PI weekly to identify challenges and reinforce the guidelines for peer mentors. During these meetings, the PI will also monitor mentors' comfort with interactions and their mentee load. If mentors express discomfort and/or feeling overwhelmed, mentees will be reassigned and/or redistributed.
5. Bi-weekly surveys to mentees and PI meetings with mentors will be used to track participant satisfaction with the peer mentoring 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. RAs 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.

In an effort to manage any high-risk aspects of the proposed work, potential mentees will be screened for depression and anxiety prior to pairing and mentors will be provided with summary sheets for each of their assigned mentees, to ensure that we are not putting mentors in a situation where they have to counsel those with serious mental health concerns (i.e., not expecting them to manage clinical depression, suicidality, etc.). Additionally, having a rheumatologist on the study team provides someone mentors can reach out to for rapid clinical feedback. When we encounter serious psychosocial (abuse, neglect, suicidal thoughts) or medical issues that need to be referred, Dr. Williams will be the primary contact for less urgent issues and responsible for linking participants to appropriate services. Dr. Oates will ensure that more urgent referrals are addressed within the MUSC hospital system. 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. To further ensure confidentiality, participants will be provided with a web-enabled phone and calling/texting/data plan for the duration of the study for mentoring and support group interactions so that personal phones are not used.

In the event of negative interactions between mentor and mentee, the following steps will be taken:

1. The PI will communicate with mentees and mentors on a bi-weekly basis to assess calling patterns, content of calls, any other interactions between mentor and mentee, and any concerns either may have.
2. Mentees and mentors will be encouraged to contact the PI at any time if they run into a difficult situation with a mentee. If during such communication, mentee or mentor reports that they believe that their mentee/mentor 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 with who they have been paired with, the PI will meet with each party individually to discuss, troubleshoot, and develop solutions or direct to services, when applicable.
3. If the mentor/mentee 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 mentor and mentee agree to continue, but report that issues can/have not been resolved, the PI will reassign to a different mentee/mentor, making every effort to match as closely as they were originally paired.
5. If complaints persist about a specific mentor or mentee that contradict study procedures (e.g., breaking confidentiality, not adhering to intervention format), that participant could be asked to leave the study.

Mid-point Analyses for the protection of participants: In an effort to protect both mentors and mentees from potential deleterious effects of mentoring, a mid-point (interim) analysis will be undertaken to assess safety using 3-month post-intervention data. If mentored participants have worsened beyond a threshold, we will stop the trial for ethical concerns. For instance, if the lower confidence limits based on 95% confidence interval at the midpoint, for any one of the variables, namely depression, anxiety, and/or disease activity, is larger than 50% compared with their baseline measure, the trial will be terminated. Similarly, mentors will be monitored for depression, anxiety, and disease activity and if a worsening trajectory is observed at mid-point analyses, they will be removed from the study.

The overarching aims of this pilot project is to test the efficacy of a peer mentoring intervention in three hundred (300) African American women with systemic lupus erythematosus (SLE) (60 mentors and 300 mentees). Our rationale is that peers who have experience in managing their lupus may be in a better position to share knowledge and experience with which others may often not be able to relate. This can establish trust and in turn decrease disparities in health care outcomes. The proposed study if successful will lead to mentees' improved health-related quality of life, self-management, and disease activity. The project is innovative because it will be the first study of its kind in this field to test peer mentorship 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.

With assistance from appropriate staff, the Principal Investigator (PI) will serve as the safety monitor for the study. The functions of the SM/PI will include: 1) provide scientific oversight; 2) review all adverse effects or complications related to the study; 3) monitor accrual; 4) generate summary reports relating to compliance with protocol requirements; and 5) guide resource allocation. The PI will review and

recommend appropriate action regarding adverse events and other safety issues. The PI will also be responsible for submitting all reports to NINR.

Study procedures and participants will be monitored throughout the course of the project to ensure patient safety and minimal risk. Study coordinators will monitor study participants at consent, all data collection encounters, and during intervention activities for any discomfort, satisfaction with study participation, and for any questions or concerns participants may have. Frequency will be determined by the rate of recruitment and enrollment. It is the study coordinator's responsibility to ensure that all returned forms are complete, intact, and transmitted to the PI and Biostatistician, as appropriate. The PI will maintain at least weekly communication with coordinators and other study team members for progress, updates, and any concerns. If a concern is raised, it will be addressed immediately. The PI will coordinate communication and/or meet with necessary parties to resolve the matter and take appropriate action (e.g., notify IRB and/or NINR, notify participant(s), amend approved IRB protocol, etc.).

On a daily basis, the PI and Biostatistician will ensure the security of all data files. At critical data collection junctures (baseline, mid-intervention, immediately post-intervention and 6 months post-intervention), the PI will review the data set to ensure de-identification prior to analysis. It is the Biostatistician's responsibility to enter, manage and analyze data, and transmit outputs and summarized results to the PI, as appropriate. On a bi-weekly basis (according to the schedule of intervention and support group sessions), the PI will monitor mentor and mentee reports of their activities and communications to ensure that they are safe and to detect any unexpected adverse events and report any concerns to the institutional IRB. Summaries of adverse events reports or patient safety concerns reported to the IRB will be made to NINR in the annual progress report unless the nature of a particular event is such that it warrants immediate reporting. If any adverse events or serious 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. The timeframe for collecting adverse events will be from the time of enrollment to last follow-up. Adverse events will be collected during each follow-up phone call or meeting by prompting participants to let the study coordinator or other research team member know if they have experienced any adverse events. In addition, should events be reported in-between follow-up calls, those will be recorded immediately. The study coordinator will inform the principal investigator of SAE and AEs by phone or secure email communication. The principal investigator will, in turn, inform the IRB immediately by updating the study record in the Health Sciences South Carolina (HSSC) eIRB system. As the PI receives notification of any study-associated adverse event, that information will be immediately shared with the overseeing IRB. Notification of an adverse or serious adverse event may be provided by the participant, MUSC study coordinator, etc. All Serious Adverse Events (SAE's) will be reported to NINR within 48 hours of the Principal Investigator becoming aware of the event.

In an effort to protect both mentors and mentees from potential deleterious effects of mentoring, a mid-point (interim) analysis will be undertaken to assess safety using 3-month post-intervention data. If mentored participants have worsened beyond a threshold, we will stop the trial for ethical concerns. For instance, if the lower confidence limits based on 95% confidence interval at the midpoint, for any one of the variables, namely depression, anxiety, and/or disease activity, is larger than 50% compared with their baseline measure, the trial will be terminated. Similarly, mentors will be monitored for depression, anxiety, and disease activity and if a worsening trajectory is observed at mid-point analyses, they will be removed from the study.

The PI will document all study activities and communications and generate formal quarterly, annual and final reports that will be disseminated to the study team and NINR program officer. At least quarterly meetings will be held with the entire study team, for regular review of research progress and for general project oversight and guidance.

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The Research Nexus and Department of Rheumatology and Immunology at the Medical University of South Carolina.

Laboratory. The laboratory consists of approximately 1700 sq feet of space in the Strom Thurmond Research Building. A tissue culture room is included in the laboratory space. Additional core space is in the Strom Thurmond building including a cold room, a warm room and a large equipment room. An additional 700sq ft of lab space is in the MUSC Children's Research Institute including a tissue culture room and core space.

Clinical. Patients at MUSC are seen in the Rutledge Tower Ambulatory Care Center. Phlebotomy services are available there and serum samples on all lupus patients seen at MUSC are currently obtained using the laboratory phlebotomy services. Patients that are part of the MUSC cohort will be seen in the outpatient clinic space of the GCRC in the Clinical Research Building.

Animal. Animals are housed in the Ralph H. Johnson animal facility that is in the Strom Thurmond Biomedical Research Building. It is an AALAC approved facility and animals are maintained under pathogen free conditions.

Computer. The laboratory has three G3/4 Macintosh computers and an additional four Dell Pentium computers. Appropriate software is installed on the computers including MacVector. Access to the GenBank is available through a server at MUSC. Each computer is connected via ethernet to the main server at MUSC for email and internet access.

Offices. Departmental heads have 125 ft2 offices adjacent to the laboratory space for personal use. One has an iMac and a G4 Powerbook computer for portable use and e other has a Dell PC and IBM laptop. An outer office suite is available for administrative personnel along with three additional offices for laboratory personnel.

Other. Administrative support for this project is provided by the Division of Rheumatology. A full time secretary is also on staff for other projects.

Major Equipment. The laboratory contains three dual block thermocyclers, two real time PCR machines, Amaxa Nucleofector device, three tissue culture hoods, three CO2 incubators, a spectrophotometer, an ELISA plate reader and plate washer, four power supplies, an electroporator, an HPLC apparatuses, a gel dryer, two table top centrifuges, water baths, various horizontal gel apparatuses, liquid nitrogen storage, a -80 freezer, two refrigerators and -20 freezers. Light, inverted, and fluoroscopic microscopes with digital camera setup are in the laboratory. A Sievers 280 nitric oxide analyzer along with analysis equipment are in the laboratory. A Molecular Dynamics Storm Phosphoimager is located in the laboratory. Both large and small screens are available as well as a Macintosh G4 computer with appropriate soft- ware. Core equipment includes an Excalibar flow cytometry machine, an Olympus confocal microscope, and an electron paramagnetic resonance imager.