**2.5 Recruitment and Retention Plan**

*Attach as a PDF file. Describe how you will recruit and retain participants in your study. You should address both planned recruitment activities as well as proposed engagement strategies for retention.*

**SAMPLE 1: NEW RECRUITMENT THROUGH RESEARCH CLINICS**

This study will recruit 30 NMO patients who are at least 18 years of age and not more than 60 years of age. These individuals will be recruited through our Multiple Sclerosis Center of Excellence, the Dean McGee Eye Institute, and other collaborating sites (please see letters of support). The Multiple Sclerosis Center of Excellence regularly follows 40 NMO patients, and the Eye Institute is one of the largest ophthalmology institutes in the United States and one of only a small handful of institutions in the Southwest and Midwest offering a complete spectrum of specialty eye care. Although we expect to recruit sufficient numbers of participants through these clinics, we can also advertise through IRB-approved, previously successful activities, such as posting to institutional websites, institutional social media posts, and advertisements in local online and print media.

After enrollment and randomization, participants will return to the clinic weekly for 4 weeks for investigational treatment and at weeks 8, 16, and 24 for clinical evaluation, labs, and biomarkers. The primary endpoint evaluation will be at week 24. In addition, participants will be seen any time during the study when symptom control becomes inadequate. Studies in our clinics have historically had high retention rates, and we do not anticipate any difficulty with retention during this relatively brief study. In the event that a participant misses a study visit, clinic staff will attempt to follow up with phone calls to the participant and/or their approved contact, and if these attempts are not successful, a registered letter will be sent to the participant. Participants withdrawn from the study will be replaced if they miss more than two of the planned five doses of study treatment.

**SAMPLE 2: NEW RECRUITMENT THROUGH THE OSCTR AND OSCTR-OBI PARTNERSHIP**

This study will recruit 148 participants who are between 40 and 75 years of age and not being treated with glucose lowering drugs (see inclusion/exclusion criteria). These individuals will be recruited through the Oklahoma Shared Clinical and Translational Resources (OSCTR) at the University of Oklahoma Health Sciences Center in Oklahoma City (please see letter of support). The OSCTR has a history of successfully recruiting representative populations for studies of this size, and we recently completed a double-blind study with a similar study design in 53 older adults (mean age 63 yrs) who met the inclusion criteria for this study. Recruitment through the OSCTR offers additional unique strategies for recruiting, such as a partnership with the Oklahoma Blood Institute that allows us to selectively reach approximately 290,000 independent blood donors based on their potential eligibility for the study. In addition, the OSCTR can recontact >1,000 previous study participants in the Oklahoma Immune cohort and >1,000 diabetes patients in the Harold Hamm Diabetes Center Registry with flyers that they can share with unaffected relatives and friends. In addition, the study can be advertised through IRB-approved, previously successful activities, such as posting to institutional websites and social media, group e-mails to OUHSC and OMRF personnel, advertisements in local online and print media, and TV coverage of the study.

After enrollment and randomization, participants will return to the clinic weekly for 4 weeks for investigational treatment and at weeks 8, 16, and 24 for clinical evaluation, labs, and biomarkers. The primary endpoint evaluation will be at week 24. In addition, participants will be seen any time during the study when symptom control becomes inadequate.

Studies in our clinics have historically had high retention rates, and we do not anticipate any difficulty with retention during this relatively brief study. In the event that a participant misses a study visit, clinic staff will attempt to follow up with phone calls to the participant and/or their approved contact, and if these attempts are not successful, a registered letter will be sent to the participant. Participants will be withdrawn from the study and replaced if they miss more than two of the planned five doses of study treatment.

**SAMPLE 3: STUDY USING NEW AND EXISTING SAMPLES FROM AN ESTABLISHED COHORT**

This study will primarily use existing samples from our Oklahoma Cohort for Rheumatic Diseases and our Oklahoma Immune Cohort, as described in the Research Strategy. In addition, this study will recruit 30 patients with SLE and 10 unaffected controls for new sample collection. These individuals will be recruited through our Oklahoma Cohort for Rheumatic Diseases and our Oklahoma Immune Cohort, from participants who have provided consent for re-contact. With the large numbers of individuals in these collections who have been historically willing to provide samples for research studies and are committed to helping with our ongoing studies we anticipate no difficulties recruiting the numbers of the subjects needed for this project. We will initially re-contact individuals from these cohorts for participation, either through scripted phone calls, IRB-approved e-mails or letters based upon the participant’s wishes. In the unusual event that we need additional participants, we can also advertise through IRB-approved, previously successful activities, such as posting to the OMRF website, OMRF social media posts, and advertisements in local online and published press.

As these are nearly all requests for on-time blood collections, retention in this specific project is not a problem. Retention within these past studies with these cohorts have been high. Although the current study design does not require collecting new longitudinal samples from the same individual, we do not anticipate trouble with collecting multiple samples from the same individual if this is needed in later years of the study. If needed to facilitate study completion, after IRB and participant approval, a FedEx kit will be sent to the participant through our OMRF Biorepository to allow procurement and shipment of samples for the final blood draw.

Date: 03/13/2019

Contact: Rebecka Bourn, PhD, OSCTR Science Writing Unit

OSCTR Website: <http://osctr.ouhsc.edu>

Funding: NIGMS award U54GM104934