**2.5. Recruitment and Retention Plan**

Our decision to advance from preclinical studies to human clinical trials is based on robust preclinical data that demonstrate the therapeutic potential of AG in reducing inflammation. In this 12-week, double-blind, placebo-controlled trial, we will enroll 80 UC patients through the IBD Clinic at Prisma Health, which serves over 50% of South Carolina’s UC population of more than 5,000 patients. Dr. Joseph Meserve, a board-certified gastroenterologist at Prisma Health, treats approximately 100 UC patients each month. This substantial patient volume positions Prisma Health as an ideal site for participant recruitment and enrollment into the study.

**Inclusion Criteria:**

1. **Age**: Male and female participants aged 18 years and older.
2. **Diagnosis**: Patients with a confirmed diagnosis of ulcerative colitis (UC), on stable 5-ASA therapy (e.g., mesalamine or its derivatives), with a UCDAI (Ulcerative Colitis Disease Activity Index) score of greater than 3.
3. **Medication**: Participants must be on stable doses of 5-ASA therapy, with allowances for prednisone taper if needed.
4. **Consent**: All participants must provide informed consent prior to study participation.

**Exclusion Criteria:**

1. **Other IBD Conditions**: Patients with Crohn’s disease, indeterminate colitis, or other forms of inflammatory bowel disease.
2. **Targeted Immunotherapy**: Patients who are currently or have recently been treated with biologics (e.g., anti-TNF therapies) or small molecule therapies (e.g., JAK inhibitors).
3. **Pregnancy/Breastfeeding**: Pregnant or breastfeeding individuals, or those with a positive pregnancy test.
4. **Surgical Needs**: Patients with an imminent need for UC-related hospitalization or surgery.
5. **Active Infections**: Participants with active infections, including HIV, hepatitis, or any other significant uncontrolled infection.
6. **Active Malignancies**: Exclusion of patients with any active cancer or those undergoing cancer treatment.
7. **Use of Investigational Drugs**: Participants currently or recently involved in another investigational drug trial.
8. **Allergies**: Patients with known allergies to Ginseng or any other ingredients in the study treatment.
9. **Medication Use**: Exclusion of participants taking medications that could bias results or pose health risks due to interactions with Ginseng or study interventions.

**Recruitment Process**: Initial contact with potential participants will be made by Prisma Health staff, led by Dr. Meserve. This will include a discussion about the study and its purpose, followed by the distribution of information and contact cards to patients who express interest and consent to further discussions via phone.

*Recruitment Strategy*:

*First meeting*: We will meet with Prisma Health staff monthly to ensure smooth flow. The first meeting will discuss study criteria and plan (below and throughout grant).

*Pre-Screen*: The pre-screen of potential participants will occur at Prisma Health Gastroenterology and Hepatology. If all criteria are met, they will be asked if they are interested in participating in a study looking at the ability of American Ginseng to ease their ailments associated with ulcerative colitis. Incentives are geared towards completion of measurements. Therefore, they are identical for all arms of the study (i.e., $50 at baseline, $50 at 6 weeks and $100 at 12 weeks). Thus, all information divulged at the time of prescreen would be applicable to each arm. At the time of prescreen, potentially eligible individuals will provide a telephone number, email address, and other relevant contact information.

*Study personnel*: The recruitment coordinator will contact all those who agreed at prescreen to participate, would be further screened to determine eligibility. The recruiters will call by phone all eligible participants and complete a standard recruitment script. All recruiters will be race-matched, as this is known to significantly improve recruitment efforts.

*Arranging first and future appointments*: Once informed consent is signed, we will arrange the first appointment with Prisma Health Gastroenterology and Hepatology. Dr. Hofseth will assign a trained team member (and if not available, will do it himself) to collect blood (embedded phlebotomist at Prisma), stool, and urine, then transport this back to the lab. If a stool sample is not available, the patient will be asked to provide one after 3 days (to allow the colonoscopy procedure impact to heal) and before 7 days.

Patient Identification: Prisma Health Gastroenterology will identify potential participants from their patient database who fit the study criteria. The USC team will engage Dr. Meserve and other gastroenterologists in the clinic to refer eligible patients to the study. The USC team will provide them with study materials and information for easy patient referral. The recruitment coordinator is the main go-between USC and Prisma Health and will be flexible.

Study Materials: We will prepare clear and concise study materials (brochures, flyers, consent forms) detailing the study's purpose, benefits, and risks. Distribute these materials in waiting areas and consultation rooms.

Online Presence: Utilize Prisma Health's and USC’s online platforms to advertise the study, providing a direct link for interested patients to contact the recruitment coordinator or access more information.

*Retention Strategy*:

We are experts and have been recognized for our high rates of recruitment and retention in the African American community as cited by the article by Greiner et al entitled ‘Effective recruitment strategies and community-based participatory research: Community Networks Program Centers’ recruitment in cancer prevention studies.’ Important factors critical to retention and that we will pay attention to are:

*Participant Education*: Conduct comprehensive orientation sessions for enrolled participants, clarifying study objectives, procedures, and expectations to promote ongoing commitment.

*Regular Communication*: Maintain regular contact with participants through phone calls, emails, or text messages to remind them of upcoming visits, assessments, or medication schedules. Samples will be picked up within an hour of a phone call.

*Convenience*: Schedule study visits at convenient times for participants, minimizing disruption to their daily routines and offering flexibility in appointment scheduling.

*Incentives*: Provide appropriate incentives, such as compensation for time and travel expenses, to motivate and retain participants in the study. $200 total will be given to each participant through visa gift cards.

*Continual Support*: Offer continuous support and address participant concerns promptly, maintaining a positive relationship between the study team and participants.

*Community Engagement:* Engage with patient advocacy groups or local community organizations to foster a supportive environment for study participants, providing a sense of belonging and encouragement throughout the trial.

By implementing these strategies, the recruitment and retention plan aims to efficiently identify eligible participants, maintain their active involvement, and ensure high retention rates throughout the NIH clinical trial evaluating American Ginseng's effects on Ulcerative Colitis patients.