**4.7. Dissemination Plan**

**4.7.a. Clinical Trials Registration and Results Submission**  
In accordance with the Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11), this clinical trial will be registered on ClinicalTrials.gov. The trial information will include key data elements such as study identification, trial status, sponsor information, study description, conditions under investigation, study design, interventions, outcome measures, eligibility criteria, investigator contact information, study locations, individual participant data sharing statements, and relevant references.

**4.7.b. Informed Consent and Clinical Trial Information Disclosure**  
As part of the informed consent process, participants will be notified that trial information, including non-identifiable summary results, will be submitted to ClinicalTrials.gov as mandated by 42 U.S.C. 282(j)(1)(A). The consent form will include a clear statement reassuring participants that personal identifying information will not be disclosed on the website, and that only general study outcomes will be made available to the public.

**4.7.c. Institutional Oversight for Clinical Trials Registration and Reporting**  
The University of South Carolina (USC) ClinicalTrials.gov administrator will support compliance with registration and reporting requirements for this trial. Dr. Lorne Hofseth, as the contact PI, will collaborate with Dr. James Hébert and the USC ClinicalTrials.gov team to ensure accurate registration and timely updates. Following USC's established Standard Operating Procedures (SOP), they will oversee the entry and confirmation of required data, update trial records as needed, and manage the submission of results and adverse events reports. Dr. Hofseth will be responsible for finalizing all reports at the end of the trial.

**4.7.c.i. Protocol Registration Data Elements**  
The study’s protocol registration will include essential results data elements, such as participant flow, baseline characteristics, outcome measures, adverse event reports, and consort diagrams. Key documents like the study protocol, statistical analysis plan, and informed consent form will be uploaded to ClinicalTrials.gov. The registration record will also include any agreements related to the delay of results and point-of-contact information for study outcomes.

**4.7.d. Study-Specific Considerations**  
This clinical trial will rigorously monitor participant safety and adhere to the highest ethical standards. Given the promising anti-inflammatory properties of American Ginseng demonstrated in pre-clinical studies, the trial is expected to show therapeutic benefits. Dr. Joseph Meserve and his team will provide continuous clinical monitoring to ensure protocol adherence and patient safety throughout the study, with particular attention to the benefit-to-risk ratio of the intervention.

**4.7.e. Dissemination of Trial Findings**  
The findings from this trial will be disseminated through several channels to reach both scientific and lay audiences. Results will be shared at national and international conferences specializing in gastroenterology, colitis, and complementary and alternative medicine. Peer-reviewed publications in high-impact journals will also be pursued to reach the broader scientific community. Additionally, outreach to patient advocacy groups and presentations to community organizations will be conducted to raise awareness of American Ginseng’s potential in treating ulcerative colitis. These efforts will help foster greater understanding of the therapeutic potential of alternative treatments for inflammatory bowel disease.