**3.1. Protection of Human Subjects**

This Human Subjects Protection Plan is designed to ensure the ethical treatment of participants and full compliance with regulatory guidelines throughout the open-label study, "American Ginseng and Panaxynol for Ulcerative Colitis: A Clinical and Preclinical Investigation."

**1. Informed Consent Process**
All potential participants will receive a clear and detailed informed consent document outlining the study’s procedures, including its open-label nature, potential risks, and benefits. Participants will have ample time to review the document, ask questions, and fully understand the study before agreeing to participate. No participant will be enrolled without providing written informed consent. The consent process will emphasize the voluntary nature of participation, and participants will be informed that they can withdraw at any time without penalty or impact on their medical care.

**2. Participant Safety and Welfare**
Participants' health and well-being will be closely monitored throughout the study. Regular assessments, including physical exams and colonoscopies, will be conducted to ensure participant safety. In the event of any new information regarding study risks, participants will be promptly informed. Adverse events will be handled with immediate suspension of study activities if necessary. A protocol is in place for early intervention in the event of any adverse reactions to American Ginseng or other study-related procedures.

**3. Confidentiality and Privacy**
Strict confidentiality protocols will be implemented to protect participant privacy. All personal data will be de-identified and coded to ensure anonymity, with only the lead investigator, Dr. Hofseth, and authorized study personnel having access to this information. Data will be securely stored on encrypted systems, and all records will be kept confidential in compliance with applicable privacy laws and institutional regulations.

**4. Risk Assessment and Minimization**
Potential risks, including side effects associated with the use of American Ginseng, will be clearly communicated to participants. Research has shown that American Ginseng is generally well-tolerated at doses up to 2 grams per day for extended periods, but side effects such as gastrointestinal disturbances, headaches, and allergic reactions are possible. To minimize risks, participants will be closely monitored with regular health assessments and appropriate safety protocols in place for adverse event management. Any serious adverse events will be reported immediately to the Institutional Review Board (IRB).

**5. Institutional Review Board (IRB) Approval and Compliance**
The study will strictly adhere to all guidelines and regulations as required by the IRB at the University of South Carolina and Prisma Health. IRB approval will be obtained prior to the initiation of the study, and any amendments or protocol changes will be promptly submitted for review. Regular reports on study progress, including any adverse events or protocol deviations, will be submitted to the IRB as required.

**6. Data Handling and Storage**
All data collected during the study will be securely stored and managed to ensure confidentiality and compliance with data protection regulations. Identifiable information will be de-identified and assigned unique codes. Data will be stored in a secure, encrypted database accessible only to authorized study personnel. Long-term storage of the data will also comply with institutional guidelines for retention and protection.

**7. Oversight and Monitoring**
The study will be regularly monitored by an independent monitoring committee, including members from the University of South Carolina IRB and internal teams from Prisma Health and USC. Weekly meetings will be held to ensure continuous oversight of study progress, safety, and data integrity. The study will also undergo periodic internal audits to ensure compliance with the approved protocol and regulatory requirements.

**8. Reporting and Documentation**
All adverse events, protocol deviations, and unexpected findings will be carefully documented. In the event of significant issues, they will be reported to the IRB and other relevant regulatory bodies in a timely manner. Complete and accurate records will be maintained to facilitate ongoing review and evaluation of the study’s safety and efficacy.

**9. Withdrawal and Voluntary Participation**
Participants will have the right to withdraw from the study at any time, without any penalties or adverse effects on their ongoing medical care. The informed consent form will clearly outline the process for withdrawal, as well as follow-up procedures to ensure participant well-being post-withdrawal. Participants who withdraw will receive appropriate follow-up care and may be asked to participate in exit interviews to document any final assessments.