**3.3. Data and Safety Monitoring Plan.**

This Data Safety and Monitoring Plan (DSMP) outlines the procedures and responsibilities for ensuring the safety and well-being of participants in the open-label clinical trial investigating the impact of American Ginseng on colitis in patients with ulcerative colitis. The primary objective is to monitor and evaluate the safety of the intervention throughout the study period.

**2. Data Safety and Monitoring Committee (DSMC):** A Data Safety and Monitoring Committee will be established to independently review and evaluate the accumulating study data. The DSMC will consist of experts in relevant fields, including gastroenterology, pharmacology, and biostatistics.

**3. Responsibilities of the DSMC:**

* Periodic review of study data to assess participant safety and study conduct.
* Provide recommendations to the Principal Investigator regarding the continuation, modification, or termination of the study.
* Review adverse events and make determinations regarding causality and severity.
* Monitor protocol deviations, enrollment rates, and overall study progress.

**4. Frequency of DSMC Meetings:** The DSMC will convene regularly at predetermined intervals, with the initial meeting occurring before study initiation. Subsequent meetings will be scheduled at least semi-annually or more frequently if required due to emerging safety concerns.

**5. Unblinding Procedures:** Given the open-label nature of the study, the DSMC will have access to unblinded data. Unblinding will only occur if there is a compelling need to assess participant safety or if directed by the DSMC.

**6. Reporting Adverse Events:** All adverse events (AEs) will be documented and reported to the DSMC promptly. The Principal Investigator will submit expedited reports for serious adverse events (SAEs) within the required timelines.

**7. Criteria for Study Modification or Termination:** The DSMC will consider the following factors when recommending study modification or termination:

* Unanticipated safety concerns.
* Significant protocol deviations impacting participant safety.
* Insufficient efficacy or futility.
* Emerging data from other relevant studies.

**8. Communication Plan:** The Principal Investigator will communicate relevant information from DSMC meetings to the Institutional Review Board (IRB), study sponsors, and regulatory authorities as necessary. Participants will be informed of any significant safety-related findings promptly.

**9. Confidentiality:** All data reviewed by the DSMC will be kept confidential. Access to unblinded data will be restricted to DSMC members and authorized study personnel.

**10. Documentation:** Minutes of DSMC meetings, including discussions and decisions, will be documented, and maintained in the study's regulatory binder. Any changes to the study protocol based on DSMC recommendations will be appropriately documented and reported to the IRB.

**11. Study Oversight:** The Principal Investigator will ensure ongoing adherence to the DSMP and promptly implement any recommendations made by the DSMC.