**Study Title:**

**Principal Investigator:**

1. Source of subjects and methods of recruitment and copies of advertisements for approval (if a “captive” population, i.e., students, is being involved, please justify their involvement)
2. Where will the project be conducted?
3. List any special instruments, technical equipment, exposure to ionizing radiation, use of recombinant DNA, or investigational devices.
4. Identify persons who will have access to specimens, results, and data, including identity of human subjects:
5. Where will consent be obtained? Where will the signed subject consent forms be stored so that they will be easily accessible in the event of on-site visits from authorities?
6. Describe any safety oversight processes:
7. Do you employ a Data Safety Monitoring Board?
   1. How is it managed?
   2. With what frequency is data reviewed for this project?
   3. How often does the Board meet?
   4. Describe any planned interim analysis:
8. If a data safety monitoring board is not utilized, describe the research plan for monitoring the data to ensure the safety of the participants. Provide the date of destruction and the ultimate means of disposal of data, and/or specimens:

Signature of Investigator:       Date: