Human Subjects Protection Plan
(This will be an appendix in your final project)

Students will develop a thoughtful and comprehensive plan that describes how vulnerable research participants will be protected during the course of the research. Be concise, but address each of the following points in turn. Please do not exceed 5 pages. (*Note: these points are abridged from the version used by the US Department of Education as well at the NCSU IRB Project Description*).

**Human Subjects Involvement and Characteristics:** Provide a description of the proposed involvement of human subjects. Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as children/minors, children with disabilities, adults with disabilities, persons with mental disabilities, pregnant women, prisoners, institutionalized individuals, or others who are likely to be vulnerable.

**Recruitment and Informed Consent:** Describe plans for the recruitment of subjects and the consent procedures to be followed. Include the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. Include a copy of recruitment materials such as emails, letters of introduction, etc.

**Collecting and Storing Data:** Describe how identifying information will be recorded and associated with data (e.g. code numbers used that are linked via a master list to subjects’ names). Alternatively, provide details on how study data will be collected and stored anonymously (“anonymously” means that there is no link whatsoever between participant identities and data). Describe management of data: security, storage, access, and final disposition.

**Potential Risks:** Describe potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

**Protection Against Risk:** Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of the subjects.

**Importance of the Knowledge to be Gained:** Discuss the importance of the knowledge gained or to be gained as a result of the proposed research. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.