Title of Project:

Graduate Student: List project coordinator(s); others may be included at the PC’s discretion.

This form describes a student project. It has information to help you decide whether or not you wish to participate. This project includes only people who choose to take part—your participation is completely voluntary. Please discuss any questions you have about the project or about this form with the project staff before deciding to participate. Please retain this copy for your records.

Introduction

The purpose of this project is to [Give a general description of the project and the kind of information that it is hoped will be gained using lay person’s terminology. For example, learn more about community attitudes towards a new recreation center; learn if attending preschool gives children an advantage when they start kindergarten, etc. Do not use scientific jargon. If the project is such that subjects must be deceived about the true purpose, explain as much as possible without jeopardizing the research.].

You are being invited to participate in this project because [Describe the reason they are being asked to participate, any inclusion criteria, in lay person’s terms (e.g., an adult runner who is not taking medication, a student in a learning community, a member of the Red Cross, etc.).] If applicable, add: You should not participate if [Describe any exclusion criteria (e.g., under age 18, have certain health conditions, etc.).].

Description of Procedures

If you agree to participate, you will be asked to [Explain ALL procedures that subjects will be asked to take part in and the information subjects will be asked to provide using lay person’s terminology (e.g., you will be asked to complete a survey about your attitudes towards alcohol use; you will be asked to walk on a treadmill for 15 minutes and then your heart rate and blood pressure will be checked; you will be asked to visit our lab once per week for the next four weeks to provide 2 teaspoons of blood; etc.).] Your participation will last for [Include the total expected duration of subjects’ participation, including the estimated amount of time needed to complete each component of the research (when relevant) and the number of visits/contacts needed.].

- The description should be clear and easy to follow. The use of bullet points, section headings, numbered steps, etc., is encouraged if it helps with readability.
- For surveys, interviews, focus groups, include a description of the types/nature of questions subjects will be asked or the topics to be discussed.
- If participants will be recorded by audio or video, this must be stated.
Risks or Discomforts

While participating in this project you may experience the following risks or discomforts: [List any and all physical, emotional, psychological, legal, pain, inconvenience, and privacy issues. Risks may include such things as embarrassment from answering sensitive questions during an interview, discomfort from a blood drawing procedure, skin irritation from application of sensors, implications from a breach of confidentiality, etc. If there are no known risks/discomforts, state that.]

Participant Rights

Participating in this project is completely voluntary. You may choose not to take part in the project or to stop participating at any time, for any reason, without penalty or negative consequences. For studies involving surveys, interviews, focus groups, or similar methods, add: You can skip any questions that you do not wish to answer.

In this section, try to anticipate concerns participants may have when choosing whether or not to participate, particularly if there are hierarchical relationships between the investigator and subjects. For example, Allen College students may be concerned about negative repercussions related to their position as a student (i.e., grades, future letters of recommendation, assistantships, etc.) if the investigator is a faculty member. Employees may be concerned about negative effects on their employment based on their choice to participate or not. These concerns can be addressed in this section by including statements that directly relate to these issues (e.g., “Your choice of whether or not to participate will have no impact on you as a student/employee in any way.”).

If applicable, list any foreseeable circumstances and/or reasons that the subject’s participation may be terminated.

Confidentiality

Records identifying participants will be kept confidential to the extent permitted by applicable laws and regulations and will not be made publicly available. However, federal government regulatory agencies [list all other applicable groups (e.g., NIH, the sponsor)], and the Institutional Review Board (a committee that reviews and approves human subject research studies) may inspect and/or copy project records for quality assurance and data analysis. These records may contain private information. If the project is regulated by the FDA, a statement that the FDA may inspect or copy records must be included.

To ensure confidentiality to the extent permitted by law, the following measures will be taken: [e.g., describe the use of any coding systems, whether identifying information will be collected or retained, etc. If identifiers will be kept with the data, this must be also stated. Also provide specific details of how data (in all formats) and any identifiers will be kept confidential (e.g., locked filing cabinet, password protected computer files, how access will be controlled, etc.).]

Describe the extent to which participants’ identities can or will be kept confidential when results of the project are disseminated. If confidentiality cannot or will not be maintained, participants should be clearly informed of this.]
Questions

You are encouraged to ask questions at any time during this project. For further information about the project, contact [project coordinator’s name and contact information; for a student project, also list the supervising faculty member’s name and contact information and Allen College’s IRB contact information. Contact information should include mailing address, phone number(s) and email addresses].