Project Title: (as it appears on the IRB application)

Name of Investigator(s): ________________________________

**Invitation to Participate:** You must provide a formal invitation to take part in the research project. For example: “You are invited to participate in a project conducted through Allen College. The College requires that you give your signed agreement to participate in this project. The following information is provided to help you make an informed decision about whether or not to participate”.

**Nature and Purpose:** State clearly and accurately what the study/project is designed to discover or establish.

**Explanation of Procedures:** Describe all procedures to be followed, including their purpose(s), duration, frequency, use of any audio or video recording, what will happen to the data/information at the end of the study/project. Include enough detail that the participant has a reasonable idea of what he/she will be doing and what he/she will be asked about. State any anticipated circumstances where the participant’s participation may end without regard to the participant’s consent.

**Discomfort and Risks:** Describe any physical, psychological, social, legal, and/or economic risk(s) or cost(s) resulting from the project. If there are no more than minimal risks--discomfort, burden, inconvenience--this should be so stated. This may be stated in one of several ways: Risks to participation are minimal. Risks to participation are similar to those experienced in day-to-day life. There are no foreseeable risks to participation.

**Benefits and Compensation:** Describe any direct benefit(s) that may result from the study/project. Benefits would include improved physical or mental health (e.g., from treatment), improved skills, etc. Compensation is distinct from benefit and would include cash, gifts, or academic credit provided for the person’s time or travel expenses. If the individual participant will receive no direct benefit, this should be stated. If applicable, describe how voluntary or involuntary withdrawal or termination affects benefits. Note that compensation should be equivalent across participant groups and cannot be used to coerce participation. That is, if compensation for time is provided, then a portion of the compensation must be provided (prorated) even if the person terminates their involvement prior to completing the study.

**Confidentiality:** State the way the participant’s confidentiality will be maintained: persons or organizations to whom information from the study/project will be furnished (including for student presentations), nature of the information furnished, purpose of the disclosure. For example: “Information obtained during this study/project that could be used to identify you will be kept confidential. The summarized findings with no identifying information may be published in an academic journal or presented at a scholarly conference”.
Right to Refuse or Withdraw: Provide information about the voluntary nature of participation and the ability of the participant to stop at any time without penalty. For example: “Your participation is completely voluntary. You are free to withdraw from participation at any time or to choose not to participate at all, and by doing so, you will not be penalized or lose benefits to which you are otherwise entitled.”

Questions: Participants should be able to seek additional information about the project. For example: “If you have questions about the study/project you may contact or desire information in the future regarding your participation or the study generally, you can contact (investigator) at 319-====-==== or (if appropriate) the project investigator’s faculty advisor _____________ at Allen College at 319-====-====. You may also contact the Allen College IRB Chair (ACIRB@allencollege.edu), for answers to questions about rights of research participants and the participant review process.”

Agreement: Include the following statement:

I am fully aware of the nature and extent of my participation in this project as stated above and the possible risks arising from it. I hereby agree to participate in this project. I acknowledge that I have received a copy of this consent statement. I am 18 years of age or older.

If the participant is unable to make a decision regarding participation, a power of attorney may sign this form. Documentation must be provided to the investigator to prove the signee is an authorized legal representative.

_________________________________     ____________________
(Signature of participant)                        (Date)

_________________________________
(Printed name of participant)

_________________________________     ____________________
(Signature of investigator)                                (Date)

[NOTE THAT ONE COPY OF THE ENTIRE CONSENT DOCUMENT (NOT JUST THE AGREEMENT STATEMENT) MUST BE RETURNED TO THE PI AND ANOTHER PROVIDED TO THE PARTICIPANT. SIGNED CONSENT FORMS MUST BE MAINTAINED FOR INSPECTION FOR AT LEAST 3 YEARS]

Additional note: Readability level is an important factor to consider when developing documents such as an informed consent. If a document is written at a level that is too high, it is likely that the reader may not fully comprehend the information presented in the document. The IRB members will be concerned with readability level because it directly impacts how well informed a potential participate will be. A good (free) website to use to check your readability level is at http://www.readability-score.com/. Please aim for an Average Grade Level of no higher than 8.