**INSTRUCTIONS**

Please provide relevant information in the sections below, replacing BLUE CAPITALIZED SECTIONS with information specific to your study, and deleting all instructions (in red) and sections that do not apply to your research as you go along. The document should be written in plain, jargon-free language that could be understood by individuals with a middle school education. Please see the [PRISM Readability Toolkit](https://kpwashingtonresearch.org/application/files/6415/5500/0956/PRISM_readability_toolkit.pdf) for guidance on improving readability. We also recommend checking your reading level at [readable.com](http://readable.com).

Please also see our [Consent Library](https://www.bowdoin.edu/grants-office/research-compliance/irb/consent/consent-library.pdf) for example language that can be used for a number of specific circumstances (e.g., use of questionnaires, focus groups, certificate of confidentiality).

**Please delete the above instructions prior to submitting the form for review.**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**KEY INFORMATION**

* **We are seeking your consent to participate in research. This research is completely voluntary.**
* **The purpose of this research is to [INSERT DESCRIPTION IN LAYMAN’S TERMS].**
* **If you consent, you will be asked to [INSERT SUMMARY OF PROCEDURES] which will require [INSERT] of your time.**
* *Choose one of the following:***We do not anticipate that being in this study will expose you to any risk of harm. OR It is possible that you will experience [INSERT REASONABLY FORESEEABLE RISK OR DISCOMFORTS] from being in this study.**
* ***Choose either of the following statements:* You will not benefit from being in this study. *OR* You may not benefit from being in this study. It is possible, however, that you [INSERT REASONABLY FORESEEABLE BENEFITS TO THE PARTICIPANT OR OTHERS] from being in this study.**
* *If the study involves an intervention or treatment for a condition for which established intervention/treatment options already exist, include the following:* **You do not have to participate in this study to receive treatment for your condition. Other treatments exist, including**[INSERT].

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

You are invited to participate in a research study titled [INSERT TITLE]. This study is being led by [INSERT NAME OF PI], a [INSERT ROLE] (e.g, student, faculty, staff member) from the [INSERT DEPARTMENT/PROGRAM] at Bowdoin College.  *If a student is leading the study, please also include:* The Faculty Advisor for this study is[INSERT NAME], from the [INSERT DEPARTMENT/PROGRAM] at Bowdoin College. *If funded:* This study is being funded by [INSERT NAME OF SPONSOR]. Approximately [X] persons will take part in this study.

Being in this study is voluntary, which means that you may choose not to join the study or to quit the study for any reason. Please read this form and ask questions before you agree to be in the study. If you decide to take part in the study, you will be asked to give your consent at the end of the form. Be sure you understand what you will do and any possible risks or benefits.

**WHAT IS THIS STUDY ABOUT?**

The purpose of this research study is to [INSERT PURPOSE].

*Provide a brief (1-3 sentence) explanation of the purpose(s) of the research. Note: If the study requires deception or incomplete disclosure, this description may be very general, incomplete or omitted. In such cases, a debriefing statement should be provided after the study's conclusion to inform participants of the research's true purpose.*

**WHAT WILL YOU BE ASKED TO DO?**

If you decide to participate in this study, you will [INSERT A DESCRIPTION OF WHAT PARTICIPANTS WILL DO].

*Clearly explain what the participant will be asked to do and the approximate time commitment of the study. All procedures listed in the IRB application and funding proposal should be described. Any procedures (interventions, manipulations, that have not been well-studied and whose effects are unknown) should be described as experimental. If the study involves an intervention or treatment for a condition for which established intervention/treatment options already exist, those alternatives should also be described here.*

**WHAT ARE THE RISKS AND DISCOMFORTS?**

***Choose either of the following statements:***

**We do not anticipate that being in this study will expose you to any risk of harm. OR**

**It is possible that [INSERT REASONABLY FORESEEABLE RISK OR DISCOMFORTS] from being in this study.**

***Reasonably foreseeable risks and discomforts might be related to the study procedures and/or a breach of confidentiality. They could include:***

* ***Physical risks (e.g., nausea, muscle aches, rashes, infection)***
* ***Psychological risks (e.g., sadness, anxiety, stress)***
* ***Legal, social or economic risks (e.g., loss of social status; negative effect on financial standing, employability, or insurability; legal consequences)***

***If you are collecting identifiable information about participants, please include the following:***

Because we will collect personal, identifiable information about you, it is possible that people who are not supposed to see your information might somehow get access to it. We will take precautions to prevent this, but we cannot ever be certain that it won’t happen.

***Note: The risks described here should match the risks described in your application.***

**Should you experience any negative effects from being in this study, please inform us as soon as possible.**

**RESEARCH-RELATED INJURY**

*Delete this section for studies that are no more than minimal risk.*

If you are injured or become sick as a result of this study, any treatment will be at your cost. Bowdoin College makes no commitment to provide free medical care or money for injuries to participants in this study.

If you have been injured or become sick because of taking part in this study, it is important for you to tell either the researcher in charge of the study (**[INSERT PI email address and phone number here])**, the Bowdoin College IRB ([irb@bowdoin.edu](mailto:irb@bowdoin.edu)), or James Kelley, Procurement and Risk Manager at Bowdoin College (jkelley@bowdoin.edu) immediately.

By participating in the research, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

**WHAT ARE THE BENEFITS?**

***Choose either of the following statements:***

**You will not benefit from being in this study. *OR***

**You may not benefit from being in this study. It is possible, however, that you [INSERT REASONABLY FORESEEABLE BENEFITS TO THE PARTICIPANT OR OTHERS].**

***Note: Compensation, gifts, l****earning about how experiments are conducted, or earning extra credit for being a research participant* ***are not “benefits” and should not be listed here.***

**WILL I BE PAID FOR BEING IN THIS STUDY?**

***Choose either of the following statements:***

**You will not be paid for being in this study. *OR***

**For being in this study, you will [INSERT DESCRIPTION OF PAYMENT].**

*Indicate whether the participant will receive any form of compensation (e.g., money, entry into a raffle, a prize, extra credit) for participating in the study.* ***If students will receive course credit for participation, ways of earning credit without participating in the research should be mentioned here. If compensation is pro-rated depending on degree of participation, please describe that here as well.***

*If identifiable information will be shared with Bowdoin administrative offices (e.g., accounts payable) to process payments, include the following:*

Your name and contact information will be shared with Bowdoin College finance staff to process your payment, but they will not receive any other information about you or details about the study.

*If participants will be paid $100-599:*

Payment for participation in research may be considered taxable income. The College is required to track compensation that is paid to you. To do this, we will ask for your name and contact information. If you receive a total of $600 or more from the College in one calendar year, you may be contacted to provide additional information (e.g., Social Security Number) for tax reporting purposes. This information is stored confidentially and is separate from other information gathered about you in this study.

*If participants will be paid $600 or more:*

Payment for participation in research may be considered taxable income. You are responsible for filing your taxes and paying the IRS any income tax you owe on your study compensation, even if you are not a US citizen. The College is also required to track and report payments that are made to you. To do this we will ask for your name, contact information, and social security number. This information is stored confidentially and is separate from other information gathered about you in this study.

**WILL BEING IN THIS STUDY COST ME ANYTHING?**

***Choose either of the following statements:***

**Being in this study will not cost you anything. *OR***

**To be in this study you will [INSERT DESCRIPTION OF ANY COSTS TO PARTICIPANT].**

**AUDIO/VIDEO/PHOTOGRAPHIC RECORDING**

***If audio, video and/or photographic recording will be done, explain:***

* ***when and what you will record***
* ***why these are needed and***
* ***what will be done with them upon completion of the research (e.g., kept for a period of time/indefinitely, destroyed after transcription).***

***If recording is optional, provide a place for participants to indicate their willingness to be recorded. For example:***

**Please indicate below if you are willing to be recorded, as described above. You may still participate in this study even if you are not willing to be recorded.**

**Audio recording:**

* **I do not want to be audio recorded.**
* **I am willing to be audio recorded.**

**Signed:**

**Date:**

**Video recording:**

* **I do not want to be video recorded.**
* **I am willing to be video recorded.**

**Signed:**

**Date:**

**Photography:**

* **I do not want to be photographed.**
* **I am willing to be photographed.**

**Signed:**

**Date:**

***If you intend to use or distribute any of the recordings or images created for this study (e.g., within publications, presentations, in educational contexts, promotional materials, etc.), separate permission must be obtained. A template for this release can be found on our website.***

**CONFIDENTIALITY**

The information that we gather about you in this study [Choose: will or will not be] linked to your identity.

*If identifiable:*

To protect the confidentiality of the information you share with us, we will [INSERT *any steps you will take to either de-identify your data or make it more difficult for individual participants to be identified should there be a breach of confidentiality. For example, you might code all study data with a number or pseudonym and either destroy identifying information or keep identifying information separate from other research data (e.g. signed consent forms kept separate from the survey data and the two will be connected by a key or not be connected).]*

The information that you share with us will be stored [INSERT where data will be kept] and will be [INSERT how it will be secured (e.g., password protected, encrypted, in a locked office]***.***

*If you are collecting and/or storing data electronically, please include the following:*

We will make every effort to ensure the security of the data that you share with us. As you are likely aware, it is impossible to completely guarantee the security of data transmitted or stored electronically. In addition to the places where we will store your information (described above), y**our data may be saved on backups and activity logs (i.e., records of internet activity).**

*If you will be communicating with participants over e-mail, include the following statement:*

Please note that email communication is neither private nor secure. Though we will take precautions to protect your privacy, you should be aware that information sent by e-mail could be read by a third party.

We will retain the information you share with us [INSERT how long you intend to retain the study data. Please note that documentation of informed consent, if obtained, must be retained for at least 3 years following the completion of the study.]

*If you are collecting identifiable information, choose one of the following two options:*

***Option 1:***

Data from this study may be used for future research studies or shared with other researchers or the research community at large to advance our understanding of this topic, without additional informed consent from you. We will remove or code any information that could identify you before data are shared to ensure that, by current standards and known methods, no one will be able to identify you from the information we share. Despite these efforts, we cannot guarantee the anonymity of your personal data.

***Option 2:***

Data from this study, even if identifiers are removed, will not be used or shared for future research studies.

*If you are collecting and retaining identifiable information, include the following:*

You have the right to withdraw your information from this study (this is sometimes referred to as “the right to be forgotten”). To withdraw your information for this study, please contact us at the phone number or email address listed below.

Only [INSERT who will have access to the data] will have access to the information you share with us.

*This next section is required for all federally funded research, and recommended for all other studies:*

It is also possible that certain people may need to review our research records and may find out about your participation in this study. For example, the following people/groups may check and copy records about this research:

· The Office for Human Research Protections in the U. S. Department of Health and Human Services

· *For sponsored studies, add:* The research study sponsor: [INSERT NAME OF SPONSOR]

· Bowdoin College’s Institutional Review Board (the committee that reviews and approves research studies)

**DO I HAVE TO BE IN THIS STUDY?**

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. If you choose to leave the study, please inform your study team to ensure a safe withdrawal from it. In either case, you will not lose any benefits to which you are otherwise entitled.

*Optional text:* You may also skip any questions or procedures that you do not wish to take part in.

**WHO SHOULD I CONTACT WITH QUESTIONS?**

If you have questions, problems related to this study, or experience any study-related injury, you should contact [INSERT PRINCIPAL INVESTIGATOR’S NAME]*,* a [INSERT ROLE (e.g, student, faculty, staff member)] at Bowdoin Collegeat [INSERT EMAIL ADDRESS]or at [INSERT PHONE NUMBER].

**WHAT IF I HAVE QUESTIONS ABOUT MY RIGHTS AS A RESEARCH PARTICIPANT?**

If you have any questions or concerns regarding your rights as a subject in this study, you may contact the Bowdoin College Institutional Review Board (IRB) at [irb@bowdoin.edu](mailto:irb@bowdoin.edu).

*Participants should be given a copy of this form—either physical or electronic. If you are conducting an online study, you may provide participants with the opportunity to download the form, should they choose.*

***Choose either of the following statements:***

You will be given a copy of this document. ***OR***

A copy of this document can be downloaded here.

*Optional:*

**PERMISSION TO BE RECONTACTED**

Please check one of the following options:

* **I do not want to be recontacted by the researcher about future research studies.**
* **I am willing to be recontacted by the researcher about future research studies.**

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

***CHOOSE ONE OF THE FOLLOWING THREE CONSENTING SECTIONS BASED ON THE INSTRUCTIONS IN SECTIONS 5 OF YOUR CAYUSE APPLICATION:***

***Option 1:***

***If you are eligible for a waiver of documentation of informed consent*** *(see section 5 of your Cayuse application for this information), participants may provide their consent in a number of ways (e.g., verbally, by checking a box, by moving forward with the survey (i.e., implied consent). Please convey how participants should convey their consent to you below.*

**If you have read the above information, have received answers to any questions that you have, and are 18 years of age or older and you wish to consent to take part in the study, please [INSERT description of how they should convey this to you].**

***Option 2:***

***If you are required to provide participants with an option for written documentation of their consent*** *(again, see section 5 of your Cayuse application for this information), please also include the following statement and the signature fields below.*

**If you have read the above information, have received answers to any questions that you have, and are 18 years of age or older and you wish to consent to take part in the study, please [INSERT description of how they should convey this to you].**

**Alternatively, if you would *prefer* to provide written consent, you may do so by signing below. This is not required.**

Your Signature Date

Your Name (printed)

**Option 3:**

***If you are NOT eligible for a waiver of documentation of informed consent*** *(see section 5 of your Cayuse application for this information), please include the following. Please note that participants should also be provided with a signed copy of this consent form.*

**I have read the above information and have received answers to any questions that I may have. I certify that I am 18 years of age or older and consent to take part in the study.**

Your Signature Date

Your Name (printed)

This consent form will be kept by the researcher for three years beyond the end of the study.