

Template for Signed Adult Informed Consent

The consent form template is provided as a guideline for researchers who will be using a formal consent document that will be signed by study participants. Insert the details that are specific to your study.

You do not have to strictly adhere to the format of the template. However, if you make changes, ensure that they make the document more participant friendly, and that you have addressed all of the required elements.

Additionally, here are some tips for creating the consent form:

- ❑ Keep the document short, simple and stick to the facts relevant to participation. Do not add more information than is necessary, include a “sales pitch,” or attempt to influence the participant.
- ❑ Consent forms should be written at an 8th grade reading level or below. Avoid use of technical terms. When using acronyms or abbreviations, spell out the full meaning the first time used.
- ❑ Compose the consent form to speak TO the participant, i.e. “You will be asked to...” instead of “The participant will be asked to...”
- ❑ The title of the study on the consent form need not match the title of the study in the project outline form. Sometimes it is better to use a simpler title for the consent form.
- ❑ Most sections are required. However, you may remove the Compensation section if no compensation will be offered to participants.
- ❑ See Basic Elements of Informed Consent for a more complete description of what should be included in each section
- ❑ See Basic Elements of Informed Consent for a more complete explanation of when a signed consent document is required and when a letter (or even briefer consent information) would be sufficient.

Bridgewater State University Informed Consent Document

Title of Research:

Researchers: *[include name, department and phone of contact person]*

You are being asked to participate in a project conducted through Bridgewater State University *[and if applicable - any other cooperating institution]*. The University requires that you give your signed agreement to participate in this project.

The investigator will explain to you in detail the purpose of the project, the procedures to be used, and the potential benefits and possible risks of participation. You may ask him/her any questions you have to help you understand the project. A basic explanation of the project is written below. Please read this explanation and discuss with the researcher any questions you may have.

If you then decide to participate in the project, please sign on the last page of this form in the presence of the person who explained the project to you. You should be given a copy of this form to keep.

1. Nature and purpose of the Project

This study is being done because...

2. Explanation of the Procedures

You will be asked to...

You should not participate in this study if... *[List exclusionary criteria, if applicable]*

Your participation in the study will last...

3. Discomfort and Risks

Risks or discomforts that you might experience are...

4. Benefits:

This study is important to science/society because...

Individually, you may benefit... **OR**

You may not benefit, personally by participating in this study.

5. Confidentiality:

Your information will be kept confidential by...

Additionally, while every effort will be made to keep your study-related information confidential, there may be circumstances where this information must be shared with:

- * Federal agencies, for example the Office of Human Research Protections, whose responsibility is to protect human subjects in research;
- * Representatives of Bridgewater State University, including the Institutional Review Board, a committee that oversees the research at BSU;
- * *[Insert sponsors of the research, if any, who will have access to identifiable data]*

Refusal/Withdrawal:

Refusal to participate in this study will have no effect on any future services you may be entitled to from the University **[and if applicable - any other cooperating institution]**. Anyone who agrees to participate in this study is free to withdraw from the study at any time without penalty.

By signing below I am indicating that I understand that it is not possible to identify all potential risks in an experimental procedure, and I believe that reasonable safeguards have been taken to minimize both the known and potential but unknown risks. **[If applicable -I agree that all known risk to me have been explained to my satisfaction. I understand that Bridgewater State University has no policy or plan to pay for any injuries I might receive as a result of participating in this research protocol.]**

Participant Signature

Date

Witness Signature

Date

Any questions regarding the conduct of the project, questions pertaining to your rights as a research subject, or research related to injury, should be brought to the attention of the IRB Administrator at (508) 531-1242.

Any questions about the conduct of this research project should be brought to the attention of the principal investigator: **[insert name(s) and contact information]**