# INFORMED CONSENT TEMPLATE

# Instructions: This template can be used for studies undergoing all types of review (i.e., exempt, expedited, full board). Below, you will find example language for required elements of consent.

# Additional information may be required for expedited and full board studies; all researchers whose research does not qualify as exempt should carefully read the checklist provided at the end of this form and incorporate all applicable information into their consent forms.

# Researchers who are planning to conduct research outside of the United States should contact the IRB for instructions on international consent and data privacy regulations.

***Delete these instructions and modify the red text below before submitting your consent form to the IRB.***

**Participant Consent Form**

You are being asked to participate in a research study conducted by [primary researcher(s) name(s) and faculty advisor, if applicable] at Hamilton College. Your participation in this study is completely voluntary. Below, you will find important information to think about when deciding whether or not you want to participate in this research.

**What is the purpose of this study?**

The purpose of this study is to [describe why this research is being conducted in lay terms. For example: “examine the types of thoughts a person may experience while performing a task.”]

[Whenever possible, when deception is used, participants should be told that they will be presented with inaccurate or incomplete information and that they will be debriefed at the end of the study. For example: “We cannot share all of the details about this study now, but we will share this information with you after you participate.”]

**What would you need to do?**

If you agree to be in this study, you will be asked to do the following:

[Provide full details about what participants will be asked to do in your study. Participants need sufficient detail about your study (e.g., the tasks they’ll do or the questions they’ll be asked) to make an informed decision about their participation. If applicable, you must identify any procedures that are experimental. Here’s an example procedure section:

1. Listen to approximately 13 minutes of one of two possible types of music (36 short melodies).

2. Report the emotion you associate with the music.

3. Complete a questionnaire in which you rate the frequency with which you have had certain types of thoughts.]

[If participants will be audio or video recorded, say so here. Provide some information about how you’ll use the recordings and how you will protect participants’ confidentiality in the way you use and store these recordings. If recordings are optional, include the following consent statement.

\_\_\_ I agree to be audio/video recorded.

\_\_\_ I DO NOT agree to be audio/video recorded.]

The total time required to complete the study should be about [X time].

**How many people will participate in this study?**

This study will include approximately X participants at Hamilton College [and/or, if applicable, other sites].

**Would you receive compensation and are there any costs to you?**

Depending on your study, choose one of the following:

* You will receive [describe payments or other compensation, e.g., extra credit in your psychology course. Describe the amount of payments/compensation and when participants will receive them.
* No, you will not receive any compensation for participating in this study.

There are no direct costs to you for participating in this study.

**What are the risks and benefits of participating in this study?**

Describe potential risks of the study.

* Some studies present no or minimal risk, in which case, you could say: “Participating in this study should not present any foreseeable risks that go beyond what you might experience in your everyday life.” If applicable, expand on any minimal risks: e.g., “You might feel some discomfort while responding to personal questions/watching video clips/etc.”
* If you foresee more substantial risks, you could say something like: “This study could present some risks to you. Possible risks associated with this study include [explain risks, how likely they are, how harmful they could be, and what you’re doing to minimize the risks.]”
* If applicable, also mention that “This study could involve risks that are not currently foreseeable.”

Describe the benefits to the participant for participating in this research. Some common benefit statements include: “There are no direct benefits for participating in this study”; “You could benefit from being in this study by [describe how participants could benefit, if applicable]”; “You will learn about the scientific methodologies of and will help contribute to the body of knowledge in [your area of study]”.

You will be informed about any new information we learn during this study that might impact your condition or your willingness to continue participating in this study.

**How will your information be protected?**

If data are being collected anonymously: The information you provide is anonymous. Your information cannot be traced back to you. The data will be accessible only to researchers working on the project at Hamilton College [and, if applicable, other research sites].

If data could be connected back to an individual participant: We will take precautions to protect the confidentiality of the information you provide to us, but we cannot guarantee total confidentiality. Study records will be kept [describe measures you’re taking to keep participant data safe, e.g., it will be kept in an encrypted drive or in a locked cabinet, interviews will be transcribed and recordings deleted].Your name will not be connected to your results or to your responses; instead, a [number or pseudonym] will be used for identification purposes. Information that would make it possible to identify you or any other participant will never be included in any sort of report. The data will be accessible only to researchers working on the project at Hamilton College [and, if applicable, other research sites]. [If you plan to collect identifiable data, you should include one of the following statements:

* Once identifying information has been removed, your results and/or responses could be used for future studies or shared with other researchers without additional consent from you.
* The information you provide in this study will not be used or distributed for future research studies.]

**Do you need to participate?**

No, your participation in this study is entirely voluntary and you may refuse to complete the study at any point or refuse to answer any questions with which you are uncomfortable. You may also stop at any time and ask the researcher any questions you may have. If you decide not to participate or to quit once you’ve started, you will not be penalized or lose any benefits to which you are entitled and your relationship with Hamilton College will not be affected in any way.

[If applicable, describe alternative procedures that might be advantageous to the participant (e.g., alternatives for receiving extra credit, therapeutic alternatives).]

**Who should you contact if you have questions?**

At this time, you may ask any questions you may have regarding this study. If you have questions later, you may contact XXX at 555-555-5555 or [XXX@hamilton.edu](mailto:XXX@hamilton.edu), or their faculty supervisor, ZZZ at 555-555-5555 or [ZZZ@hamilton.edu](mailto:ZZZ@hamilton.edu). Questions or concerns about institutional approval should be directed to [Name of current IRB Chair], Chair of the Institutional Review Board for Human Subjects, at [iboard@hamilton.edu](mailto:iboard@hamilton.edu). If you feel you have been harmed in any way as a result of this study, please contact XXX at 555-555-5555 or [XXX@hamilton.edu](mailto:XXX@hamilton.edu) [*this is typically the name and info of the faculty member in charge of/supervising the research*].

You may [ask the researcher for/print a copy of] this consent form now for your records.

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**Statement of Consent:**

[If you will be having participants sign the consent form] By signing below, I agree that… OR [If electronic or not obtaining signed consent forms] By [clicking below, verbally agreeing, continuing to the next page, answering interview questions, etc…], I agree that…

I have read the above information regarding participation in this research. I have asked any questions I had regarding the study procedure and they have been answered to my satisfaction. I consent to participate in this study.

[If providing paper consent forms] I received a copy of Hamilton’s Privacy Notice and I read and understood it. OR [If consenting online] I have been provided a link to [Hamilton’s Privacy Notice](https://www.hamilton.edu/privacy) and have read and understood it.

I consent to the processing of my personal data and special categories of personal data in accordance with the Privacy Notice and for the purposes of applying to and participating in Hamilton College research studies.

[If there is any chance you’ll recruit participants outside of the U.S. include the following statement:] If I reside outside of the United States, I consent to the cross-border transfer of my personal data and special categories of personal data as set out in the Privacy Notice.

[For signed consent forms use the following signature lines.]

|  |  |
| --- | --- |
| Signature of participant | Signature of researcher |
| Printed name of participant | Printed name of researcher |
| Date | Date |

[All researchers should verify that participants using this consent form are at least 18 years old before conducting their study.]

Age: **(Note: You must be 18 years of age or older to participate in this study. Let the researcher know if you are under 18 years old.)**

**INFORMED CONSENT CHECKLIST**

***This information is for researchers only. Delete checklist before submitting your consent form to the IRB.***

**General Requirements for Informed Consent (45 CFR** [**46.116**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116)**):**

1. Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject’s legally authorized representative.
2. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
3. The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.
4. The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
5. Informed consent must:
   1. begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
   2. present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject’s or legally authorized representative’s understanding of the reasons why one might or might not want to participate.
6. No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

**Required elements of consent (**[**45 CFR 46.116(b)**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116)**):**

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others that may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights, and whom to contact in the event of a research-related injury to the subject;
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
   1. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
   2. A statement that the subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

**If applicable, include the following (**[**45 CFR 46.116(c)**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116)**):**

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;
2. Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s or the legally authorized representative’s consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research that may relate to the subject’s willingness to continue participation will be provided to the subject;
6. The approximate number of subjects involved in the study;
7. A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).
10. Describe the amount and schedule of payments to participants
11. If participants’ responses could trigger mandated reporting requirements (e.g. they report abuse or neglect, threats to self or others), the consent informs participant of this possibility
12. If the researchers have obtained a Certificate of Confidentiality (CoC), the consent describes the protections, restrictions, and exceptions of the CoC

*\* Note: If applicable, researchers are responsible for incorporating additional elements of consent which are not listed here but are required by their funding agency (e.g., NIH) or the FDA.*