

MARQUETTE UNIVERSITY CONSENT FORM INSTRUCTIONS with Template

Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. As part of the informed consent process, it is vital that the consent form be clear and understandable. Delays in the approval of IRB applications most commonly result from the submission of inadequate consent forms. These guidelines are intended to assist investigators in the creation of their consent form documents and to address issues that commonly arise.

HOW TO: The **orange text** in the consent form template at the end of this document is intended to be instructional and offer helpful hints. When creating a consent form from the template, please remove all text in orange prior to submission to our office. A separate Word document template is available for you to download and use.

Please note that the Institutional Review Board (IRB) requires the use of the consent form template for subjects ages 18 and older. If you wish to use a different format, you must state in your application a **compelling** reason in order for the IRB to accept the use of a different format.

MINORS as research subjects: In the state of Wisconsin minors are considered to be persons under age 18. Minors are not able to give consent, but can give assent. Parents or legal guardians must give their permission by signing the consent form for the consent to be valid.

GENERAL INSTRUCTIONS

1. The IRB requires the use of an “approved” consent form indicated by an approval stamp. The ORC will stamp an original consent form as the approved final version. The stamp will indicate the consent form’s initial approval date. The stamped consent form will be sent to the principal investigator with the protocol approval letter. The stamped consent form is to be copied by the investigator and distributed to all potential participants. Once the subject has signed the consent form, the investigator should provide a copy of the signed form to the subject for their records.
2. The consent form should be written in either the first person/participant’s voice (e.g., I will be asked to watch a demonstration on the use of training techniques and then complete a survey) or the second person’s voice (e.g., you will be asked to watch a demonstration) so the consent form is consistent throughout the document.
3. Please include a space for "Protocol Number" and if your consent form is multiple pages, please include page numbers (i.e., Page X of Y). A space for the “Protocol Number” is provided in the template. This number is assigned to the protocol by the ORC. We will write in the number on the approved consent form, or if you know the number you can include it yourself on the consent form submitted to our office for review. If your consent form is longer than one page, please include spaces for participants to initial and date at the bottom of all non-signature pages.

4. A consent form written in technical language or containing jargon often will be deemed incomprehensible and intimidating to a potential participant. Please make every effort to write for the intended audience by using language appropriate for the participants' age group and education background. Use lay language when possible. Keep in mind that many adults read at an eighth grade level. [To check the readability level in Microsoft Word, go to the Tools menu, click Options, click the Spelling & Grammar tab, and under Grammar select the 'Show readability statistics' check box and click OK. Go to the Tools menu and run the Spelling and Grammar check – after the spelling and grammar check is complete, it will list the Flesch-Kincaid Grade Level.]
5. When your application uses consent forms for different subject groups (students, teachers, parents, control groups, etc.), please identify the appropriate subject group in the title of the consent form. For example, stating "Marquette University Agreement of Consent for Research Participants – Students" or "Parent Consent Form" at the top of the form will assist our review of your application and will help you to keep them organized.
6. When conducting blood draws, biopsies or administering a procedure using metric measurements, please translate the measurements into a commonly recognized amount. For example, if you will draw 15 cc of blood, state that amount in teaspoons or tablespoons. If you will conduct a bone scan, identify the amount of radiation exposure in terms understandable by the participant, such as the amount relative to a routine dental X-ray. If hearing experiments are conducted, compare the noise level to common noises (e.g., this decibel level is comparable to the sound of a vacuum cleaner).
7. In the "Confidentiality" section of the consent form, describe the procedures you will use to ensure the participant's confidentiality. Describe where data, including audio, video or other image recordings, will be stored, preferably in a secure location (perhaps a locked cabinet) on campus. Also indicate how long the data will be stored including when and how the data will be disposed. If data are stored indefinitely, state this. If you choose to conduct **focus groups**, you must disclose that even though you instruct participants the discussion is confidential, you cannot guarantee that all focus group participants will respect everyone's confidentiality. If your research is regulated by the Food and Drug Administration, this section needs to indicate that the research records may be inspected by the Food and Drug Administration.
8. Special issues with compensation. The federal regulations do not consider participant compensation to be a direct benefit of research in the same way the use of an experimental drug for a medical condition might be beneficial. If you compensate your participants with money or a gift, please provide that information in the consent form under the "Compensation" section. Describe the amount of compensation, how and when it will be distributed, and in what form.
9. Special issues with consent forms for non-English speakers. If recruiting participants who do not speak English, please submit copies of the consent form in both English and in the language spoken by participants. The IRB/ORC does not provide translation services.

Consent forms are only approved in English and it is the responsibility of the investigator to have the approved English version translated into the non-English language being used.

- 10.** Special issues with parental consent forms. If conducting research in primary or secondary schools, state and federal law require that parents and guardians be allowed to review instructional materials or research instruments. Please state in your parental consent form that parents can at any time request the opportunity to review any of the instruments, surveys, etc. Additionally, although you are not required to procure the signature of both parents for minimal risk studies, we request that you attempt to procure consent from both parents and provide spaces for both parents' names and signatures on the parental consent form.
- 11.** The consent form must contain information regarding the risks and benefits of participation. For research qualifying for expedited review, the risk is minimal. Minimal risk is no greater than everyday experiences. Additionally, other risks may be identified, such as breach of confidentiality or risk of infection and bruising with blood draws. The description of benefits should be limited to direct benefits to the participants or benefits to others that can be reasonably expected from the research. If there are no direct benefits, please state this.
- 12.** Assent forms should be written appropriate to the age group of the subjects. Our website has a sample assent form. However, it should be modified as appropriate for the age group. Children ages 16 and older should have an assent form that complies with the IRB's consent form template. If you are conducting research with a wide age range of children (e.g., 3rd grade through 12th grade), it could be beneficial to have three different assent forms to adequately accommodate those subjects. Additionally, for young children who do not read and write well, an assent form may not be appropriate. Rather, a verbal assent process where the researcher reads the information to the child and the child is allowed to verbally assent can be used.
- 13.** For research conducted in clinic or business establishments, please state under "Voluntary Nature of Participation" that participation in the research will not affect their ongoing relationship with the clinic or affect their treatment or employment, etc.
- 14.** If your study will require subjects to be responsible for any costs of participating in the research, that information should be included in the "Extra Costs to Participate" section of the consent form. Extra costs to participate may include, but are not limited to, transportation costs to and from the study site, costs of medicines or other treatments, costs of study related supplies, etc. If there are no extra costs to participate in the study, please delete this section.
- 15.** Consent forms should have 1" margins and use at least a 12-point font.

Protocol Number: _____

MARQUETTE UNIVERSITY
AGREEMENT OF CONSENT FOR RESEARCH PARTICIPANTS

(insert title of project)
(insert Principal Investigator's name)
(insert Academic Department)

You have been invited to participate in this research study. Before you agree to participate, it is important that you read and understand the following information. Participation is completely voluntary. Please ask questions about anything you do not understand before deciding whether or not to participate.

PURPOSE: The purpose of this research study is (This should be a short, concise, statement that can be clearly understood by individuals with no knowledge of the researcher's field – avoid all jargon.) You will be one of approximately X participants in this research study.

PROCEDURES: (This should be a step-by-step account of procedures as observed/experienced by the participant. For audio or video taping, include a statement such as “You will be audio taped during the interview portion of the study to ensure accuracy. The tapes will later be transcribed and destroyed after X years beyond the completion of the study. For confidentiality purposes, your name will not be recorded.”)

DURATION: Your participation will consist of (This should inform the potential participant of the number of sessions, minutes, hours, days, etc. they will be actively engaged in the research.)

RISKS: The risks associated with participation in this study include (No study is without risk. If the risks are minimal, please state that the risks are no more than the participant would encounter in everyday life. If there are identifiable risks, list the risks and describe the safeguards in place to avoid these risks. Depending on the type of research you are conducting, you may become privy to information that triggers the mandatory reporting requirements for child abuse, child neglect, elder abuse or intent to harm self or others. In these types of research, this must be disclosed as a risk to participants.)

BENEFITS: The benefits associated with participation in this study include (Benefits refer to direct benefits. Research sometimes provides subjects with treatment, diagnosis or examination for an illness or condition. In these cases the research involves evaluations that may benefit the subjects by improving their condition or provide a better understanding of their condition. Investigators should clearly detail these potential benefits in the consent form, while not overstating these benefits. Additionally, benefits cannot be guaranteed. Not every study has direct benefits to subjects. If the study does not have direct benefits to subjects, state this. You can also include a statement that participation may help provide a better understanding of the topic you are researching.)

CONFIDENTIALITY: All information you reveal in this study will be kept confidential. All your data will be assigned an arbitrary code number rather than using your name or other information that could identify you as an individual. When the results of the study are published, you will not be identified by name. The data will be destroyed by shredding paper documents

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and deleting electronic files (number of years or months etc.) after the completion of the study. (A statement describing procedures taken to protect the privacy and confidentiality of the participant. Describe how, where, and for how long data will be stored plus how the data will be disposed of and any anticipated use of the data in the future. In addition, describe how tapes (if used) will be maintained and when they will be erased. Also, discuss the limits of the confidentiality. For example, if focus groups are used, you cannot assure that other participants will maintain the subject's confidentiality and privacy (such as "All focus group participants are instructed to keep discussions confidential. However, the researcher(s) cannot guarantee that all focus group participants will respect everyone's confidentiality.")). For research that is regulated by the Food and Drug Administration, please include a statement that indicates the research records may be inspected by the Food and Drug Administration.) Your research records may be inspected by the Marquette University Institutional Review Board or its designees, (insert study sponsor if sponsored by a funding agency, and the FDA for research regulated by the FDA) and (as allowable by law) state and federal agencies.

COMPENSATION: (Delete this section if not applicable. If applicable, describe the amount of compensation, how and when it will be distributed, and in what form. The key issue the IRB will evaluate is the potential for compensation to be coercive. If pro-rated payments will be paid to subjects for early withdrawal or another purpose, that information needs to be clearly stated.)

EXTRA COSTS TO PARTICIPATE: (Research sometimes requires subjects to pay out of their pocket for certain aspects of the research study. This can include, but is not limited to, transportation costs to and from the study site, costs related to medicines or other treatments, costs of study related supplies, etc. If there are no extra costs to subjects, delete this section.)

INJURY OR ILLNESS: (This section is not required unless this project involves more than minimal risk.) Marquette University will not provide medical treatment or financial compensation if you are injured or become ill as a result of participating in this research project. This does not waive any of your legal rights nor release any claim you might have based on negligence.

VOLUNTARY NATURE OF PARTICIPATION: Participating in this study is completely voluntary and you may withdraw from the study and stop participating at any time without penalty or loss of benefits to which you are otherwise entitled. (Indicate the procedure for a participant to withdraw his/her data. Although participants should be able to withdraw their participation at any time, situations do occur during the research process making that difficult or even impossible. For example, if at some point during the research project the data will be de-identified, it may not be reasonable to find and extract a particular person's data from the data set. In this section, also indicate what will happen to the data if participants withdraw.)

CONTACT INFORMATION: If you have any questions about this research project, you can contact (insert PI name and contact information, plus the name and contact information for any additional research personnel that also serve as a contact for participants.) If you have questions or concerns about your rights as a research participant, you can contact Marquette University's Office of Research Compliance at (414) 288-7570.

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I HAVE HAD THE OPPORTUNITY TO READ THIS CONSENT FORM, ASK QUESTIONS ABOUT THE RESEARCH PROJECT AND AM PREPARED TO PARTICIPATE IN THIS PROJECT.

Participant's Signature

Date

Participant's Name

Researcher's Signature

Date