**INFORMED CONSENT FORM:**

**WAIVER OF DOCUMENTATION OF INFORMED CONSENT**

**NOTRE DAME OF MARYLAND UNIVERSITY**

[Instructions: Use this template to prepare your consent form if you are requesting the IRB for a waiver of documentation of informed consent. How to use it:

* ***Bolded, italicized, purple text*** found throughout the template offers instructions – where appropriate, replace this text with the appropriate wording for *your* project.
* Aim to make your informed consent document complete, but concise, and use lay-friendly language.
* In the final version: Remove all unnecessary wording and instructions/italicized text, change font color to black, and submit a pdf copy to the IRB.
* If you are conducting research with people under the age of 18, include two separate consent documents, based on this template: 1) a **Parental Permission Form** to ask parents for consent to the participation of their child, containing all of the elements of this template and written in language appropriate for parents giving permission for their child’s involvement rather than their own (e.g., “we are inviting your child to participate,” “the risks to your child include”, etc.). 2) an **Assent Form** that asks minors if they agree to take part in the research, depending on whether the children are capable of assenting (based on age, maturity, psychological state). Assent forms should be written in age-appropriate language.
* If you are conducting research with people with impaired decision-making capacity, prepare a consent form (using this template) to ask the research subject’s authorized representative for consent to the participation of the research subject. Prepare an **Assent Form** to ask research subjects if they agree to participate in the research, depending on whether they are capable of assenting, based on their decision-making capacity.

**Additional Guidance on Waivers of Documentation of Informed Consent:** An IRB can waive the requirement for the investigator to obtain a signed consent form for some or all subjects under certain conditions. This is known as “waiver of documentation of informed consent” and can be used when either of these two conditions apply:

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality;[[1]](#footnote-1) or
2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context (e.g., drawing a blood sample, or asking shoppers in a mall about the ambient lighting or temperature).

In this case, even if there is a waiver of the requirement for a signed consent form, the investigators must still perform an informed consent process that meets the requirements for obtaining informed consent (and describe to the IRB how this will be done). This means there must still be an active process in which the investigators (1) disclose to potential research subjects the information they need to make an informed decision; (2) facilitate their understanding of what has been disclosed (e.g., ensuring consent language is readable and lay-friendly, making sure they know they can ask questions, and how); and (3) promoting the voluntariness of the decision about whether or not to participate in the research.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or the parents of children who are subjects with a written statement regarding the research (printed or available for download).

**If you intend to ask the IRB for a waiver of documentation of informed consent, your IRB application materials must document that your study meets the above criteria, and that you will perform an informed consent process, and that you will provide a copy of the informed consent document for participants who wish to have one.**

Whether or not a subject signs a consent form, some might not wish to have a copy of the consent form out of concern that their possession of the form could compromise their privacy. This is fully consistent with the idea behind one of the bases for a waiver of the requirements for documentation of informed consent - that harm would result to the subject if his/her identity were compromised by the documentation itself.

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html>

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| **PROJECT TITLE** | ***[Use the same title in the IRB application.]*** |
| **Why is this research** **being done?** | This is a research project being conducted by ***investigators’ names*** at Notre Dame of Maryland University. We are inviting you to take part in this research project because you ***[Describe why the person reading the consent form is a possible research subject for your project].***  The purpose of this research project is ***[describe the knowledge or information that is being sought and explain why you are seeking the knowledge or information].*** |
| **What will I be asked to do?** | If you take part in this study, you will***[Describe the procedure(s) chronologically******using lay language and short sentences. State the location where the study will be conducted. Explain educational, medical and other technical terminology using simple language. State the overall duration for the subject’s participation and, if appropriate, how long each procedure will take. If the research involves surveys or interviews, include a detailed description of the questions. Identify experimental procedures. Describe alternative procedures or courses of treatment, if any that might be advantageous to the subject.].***  ***If you are using audiorecordings/videorecordings/photographs in this study, include a description of what recordings/images are being made and why, who will have access to them, where they will be stored, and when (or if) they will be destroyed.*** |
| **What about** **confidentiality?** | We will keep your personal information confidential. To help protect your confidentiality***[Include a description of the******procedures to maintain the confidentiality of the data, e.g. having locked filing cabinets and storage areas, using identification codes only on data forms, and using password-protected computer files.***  ***For anonymous surveys, state that “the surveys are anonymous and will not contain information that may personally identify you”.***  ***For coded identifiable information, state the following, if applicable (1) your name will not be included on the surveys and other collected data; (2)******a code will be placed on the survey and other collected data; (3)******through the use of an identification key, the researcher will be able to link your survey to your identity; and (4) only the researcher will have access to the identification key.***  ***[If there is a possibility that you will collect information on child abuse or neglect, abuse or neglect of the developmentally disabled or other vulnerable adults, danger to the subject or others, or similar types of information that may need to be disclosed to comply with******legal requirements, professional standards, etc., the possibility of such disclosure must be included in the consent form. See the following example, and modify it to include all applicable types of information.***  ***If there is a possibility that you will collect such information, but you******do not intend to disclose it, you must provide an explanation and any justification for non-disclosure in your IRB Application.]*** |
| **What are the risks** **of this research?** | ***Describe any known risks including physical, psychological, social,******emotional, legal and financial risks that may result from participating in the research. Some studies include risks that may be better described as things that could make the subject feel uncomfortable such as fear, embarrassment or fatigue. These are also examples of risks that should be included.***  ***Do not describe risks as minimal and******do not state that there are no risks beyond everyday life.*** |
| **What are the** **benefits of this research?** | The benefits to you include ***[only list the direct and reasonably******expected benefits to the subject. It is acceptable to say “you may not personally benefit from this study.” Monetary compensation and extra credit for courses are not benefits and should be described in the “What will I be asked to do?” section]***  We hope that, in the future, other people might benefit from this study through improved understanding of [***Describe the anticipated benefits to science or society expected from the research, if any].*** |
| **Do I have to be in** **this research?**  **May I stop being in the study at any time?** | Your decision to take part in this research is completely voluntary. You may choose not to take part at all. If you decide to take part in this research, you may stop taking part at any time. If you decide not to be in this study or if you stop take part at any time, you will not be penalized or lose any benefits to which you otherwise qualify.  ***If applicable, include an explanation of any circumstances under which a subject’s participation may be terminated by the investigator without regard to the subject’s consent.***  ***If applicable, include an explanation of the consequences of a subject’s decision to withdraw from the research and any procedures for orderly termination of a subject’s participation.***  ***If you are collecting data within a classroom, include a statement that participation is not a course requirement. If course credit is offered for participation, include a statement that students have other options for earning course credit, and describe them. The options should not be more difficult than participating in the research.***  ***If you are conducting research with prisoners, include a statement indicating that the decision to participate or not will not affect or influence the length of their sentence, parole, or any other aspect of their incarceration. Also include a statement that deciding to take part in the study and leaving before the study is over will likewise not affect or influence the length of their sentence, parole, or any other aspect of their incarceration.*** |
| **What if I have** **questions?** | This research is being conducted by***[principal investigator’s name and******department]*** at Notre Dame of Maryland University. If you have questions or concerns about the research study itself, please contact***[principal investigator’s name]*** at *[****Principal investigator contact information].*** The Institutional Review Board (IRB) is an independent group of people at Notre Dame of Maryland University who oversee human subjects research; if you have questions or concerns you may also contact the IRB at[**irb@ndm.edu**](mailto:irb@ndm.edu)or contact the IRB Chair ***[name of present IRB chair]*** at ***[IRB Chair contact information].*** |
| **Consent**  **Please note: Parental consent always needed for minors.** | You do not have to sign a consent form to be in this study. You may have a copy of this document if you would like one for your records. You do not have to take a copy of the document if you do not wish to have one.  In agreeing to take part in this study, you agree that:   * you are at least 18 years of age; * the research has been explained to you; * your questions have been fully answered; and * You freely and voluntarily choose to take part in this research project. |

***\*\*\*\*Please note: When the consent form requires more than one page, there is a space*** ***for the subject to initial and date at the top right-hand corner of each page. This additional information would confirm that the subject agreed to the entire contents of the consent form. \*\*\****

1. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject’s wishes will govern. [↑](#footnote-ref-1)