

**Guidelines for Constructing an Informed Consent Document**

***\*\*Use this template for non-exempt (i.e., expedited or full board-reviewed) protocols that are NOT subject (or potentially subjected) to the General Data Protection Regulation (GDPR).***

***Note: Studies involving electronic data collection of identifiable personal information are potentially subject to the GDPR, unless steps are taken to ensure participants are not providing data from a European Union location.***

***Note: This template should not be used for FDA regulated studies. Please contact the Office of Research Compliance and Integrity (616-331-3197;*** ***rci@gvsu.edu******) if you are planning a clinical study.***

*Use GVSU letterhead. Include all of the information indicated below as appropriate to the study. Headings in* ***BOLD RED CAPS*** *are required on all consent forms; headings in* ***BOLD BLUE CAPS*** *are additional requirements that must be included only when they apply to your study.**For most sections the information should be expressed in a few simple sentences. Text should be written at a level consistent with your target participants. For the general public, this should be* ***written at a 6th-8th grade reading level***. *You can assess the reading level of your text using Microsoft Word (see the end of this document for more details).*

*The Key Information box must fit entirely on page 1. For minimal risk research, information presented in this box does not need to be repeated below as long as the information in the box is complete and no further explanation is needed. If additional explanation is needed, include this in the corresponding section later in the document.*

**TITLE** Research Study Title

**RESEARCHERS** List names of principal investigator(s) and other key personnel. If investigator(s) are students, you must also include faculty advisor by name and department.

“You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when making a decision whether or not to participate. Carefully consider this information and the more detailed information provided below the box. Please ask questions about any of the information you do not understand before you decide whether to participate.”

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| **Key Information for You to Consider** |
| * **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
* **Purpose**. The purpose of this research is [provide a brief description of why the research is being conducted, no more than 2-3 sentences].
* **Duration.** It is expected that your participation will last [expected duration].
* **Procedures and Activities.** You will be asked to [briefly highlight the key research activities/procedures].
* **Risks.** Some of the foreseeable risks or discomforts of your participation include [describe the most important risks. Consider those most probable and/or highest magnitude of harm].
* **Benefits**. Some of the benefits that may be expected include [insert direct benefits, or if no direct benefit to subject state no direct benefit but the researchers hope to learn/gain xyz].
* **Alternatives.** As an alternative to participation, you could [note appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the prospective subject. If there are no alternatives, state, “Participation is voluntary and the only alternative is to not participate.”].
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1. **PURPOSE** Clearly indicate it is a research study and state the purpose of the study. If this was clearly and completely explained in the key information box, delete this section.
2. **REASON FOR INVITATION** State the reason for inviting individuals to participate. If applicable, include a brief summary of relevant inclusion and exclusion criteria.

# PROCEDURES

If this was clearly and completely explained in the key information box, delete this section.

* + Briefly describe all procedures participants will perform, and their location.
	+ State approximate time required for each procedure.
	+ Indicate which procedures are experimental, if any.
	+ Specify out of pocket costs to participants, if any.
1. **RISKS** If all known risks were clearly and completely explained in the key information box, delete this section. Describe the known risks to participants from participating in the research itself, if any. Include likelihood of each risk: minimal risk, slightly greater than minimal risk, or significant risk. If collecting/storing electronic data, a statement similar to the following must be included: “Electronic data will be collected and/or stored for this research project. As with any use of electronic means to store data, there exists a minimal risk that data could be lost or stolen.” If a treatment or procedure may involve risks to the subject (or embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable, this must be included.
2. **COMPENSATION FOR HARM** State “If you are harmed from participating in this research, contact: [insert name and contact information]. Emergency first aid will be provided to you, and you will be referred to an appropriate medical care center. Any costs for additional medical care that may be required are your responsibility and that of your medical insurance company.”

**Note: Do not include this section if there are no anticipated physical harms from participating in the research.**

1. **POTENTIAL BENEFITS TO YOU** Describe the potential direct or indirect benefits to participants from participating in the research. If none, state none. Compensation for participation is not a benefit. If all benefits were clearly and completely explained in the key information box, delete this section.
2. **POTENTIAL BENEFITS TO SOCIETY** Describe the anticipated direct or indirect benefits to society from completion of the study and dissemination of results. All studies should include at least one potential benefit to society. Do not exaggerate the potential for benefit. If all benefits were clearly and completely explained in the key information box, delete this section.
3. **ALTERNATIVES TO PARTICIPATION** If applicable, list alternatives to participating in the research. If the alternatives were clearly and completely explained in the key information box, delete this section.
4. **PRIVACY AND CONFIDENTIALITY** State the extent, if any, to which confidentiality of records identifying the participants will be maintained. For example, “Your name will not be given to anyone other than the research team. All information collected from you or about you is for the sole purpose of this research study and will be kept confidential to the fullest extent allowed by law. In very rare circumstances specially authorized university or government officials may be given access to our research records for purposes of protecting your rights and welfare or to make sure the research was done properly.”

If this research is funded by the NIH, include the following: “A Certificate of Confidentiality has been obtained from the Department of Health and Human Services for this study. To help protect your privacy, this certificate prevents researchers from being required (subpoenaed) to disclose identifying sensitive information collected for this study for use in court in most cases.”

1. **PERSONAL DATA** State “Personal data to be collected in this study includes: [INCLUDE ALL THAT APPLY FOR YOUR STUDY] personal identifiable information (such as name or email address), demographic data, racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic/biometric data, health data, and data concerning your sex life or sexual orientation. Sensitive personal data will be handled and processed only by researchers conducting this study, or by specially authorized university or government officials to make sure the research was done properly.”
2. **DATA TRANSFER** State “If you provide data to the researchers of this study while you are physically located outside of the United States, your data will be transmitted to a Grand Valley State University campus in the United States for processing.”
3. **DATA SECURITY** State “GVSU is committed to keeping your data secure. We have put in reasonable physical, technical, and administrative data protection measures for this research. If you suspect a data breach has occurred, please contact the Vice Provost for Research Administration at Grand Valley State University, 1 Campus Drive, Allendale, MI. Phone: 616-331-3197. E-mail: rci@gvsu.edu.”
4. **DATA RETENTION** State “Personal data will be retained for [insert period of time] following the completion of this research.”
5. **WITHDRAWING CONSENT** State “You have the right to withdraw your consent to the collection and processing of personal sensitive data at any time. If you would like to withdraw from participating in this study, please contact the lead researcher: [insert name and contact information]. If you would like to request that your personal data be removed from this study, please contact the Vice Provost for Research Administration at Grand Valley State University, 1 Campus Drive, Allendale, MI. Phone: 616-331-3197. E-mail: rci@gvsu.edu.”

**Note: The university requires data removal requests to go through the Vice Provost for Research Administration (VPRA) to ensure compliance with the General Data Protection Regulation. The PI will be contacted by the VPRA and/or ORCI with further instructions in the event any requests for data removal are received.**

1. **RESEARCH WITH TISSUE, BLOOD, SALIVA OR URINE** If the research involves collecting biospecimens, the following statements must be included.
* 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.
* A statement regarding whether clinically relevant research results, including individual research results, will be provided to subjects, and if so, under what conditions.
* A statement whether the research will or might include whole genome or exome sequencing.
1. **AFTER THE STUDY IS OVER** Research that collects identifiable private information, even if only temporarily, must include the following statements.

“The research team will OR will not keep your research data to use for future research.”

“Your name and other information that can directly identify you will be kept secure and stored separately from the research data collected as part of the project. OR Your name and other information that can directly identify you will be deleted from the data collected as part of the research.”

“The research team may share your research data with other investigators without asking for your consent again, but it will not contain information that could directly identify you. [If the data must or will be deposited in a public or other repository, briefly describe.] OR The research team will not share your research data with other investigators.”

1. **RESEARCH STUDY RESULTS** If applicable, state “You will be informed about any significant new findings developed during the course of the study that may relate to your willingness to continue participating in the study.

If you wish to learn about the results of this research study you may request that information by contacting: ­­­­­­­­­­­­­­[insert name and contact information].”

If the research involves clinical testing, include a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

If the research is federally funded and is required to be listed on clinicaltrials.gov, the following language must be included exactly as written: “A description of this clinical trial will be available on [www.clinicaltrials.gov](http://www.clinicaltrials.gov), as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.”

1. **PAYMENT** Describe any payment for participating in the research study that will be offered to all participants. This may be as compensation for time and effort or as an incentive to participate. Incentives must be minor and may not constitute undue influence to participate. If the incentive involves entering a drawing for a prize, describe the drawing, prizes, and approximate chances of winning. If there is no payment, delete this section.
2. **REMOVAL FROM STUDY** Describe the consequences of a subject’s voluntary withdrawal from the study, if any, and procedures for orderly termination of participation. State what will be done with collected data if the participant withdraws from the research. If applicable, describe circumstances when participation may be terminated by the researcher without the participant’s consent.
3. **AGREEMENT TO PARTICIPATE** In studies enrolling adult participants only, state “By signing this consent form below you are agreeing to the following:
	* The details of this research study have been explained to me, including what I am being asked to do and the anticipated risks and benefits;
	* I have had an opportunity to have my questions answered;
	* I am voluntarily agreeing to participate in the research as described on this form;
	* I am voluntarily agreeing to have my personal data used for this study and agree the data can be transferred to the United States if originally collected outside of the United States;
	* I may ask more questions or quit participating at any time without penalty.

Print Name:

Sign Name in ink:

Date Signed: ”

**Note: In studies enrolling minors (persons not yet 18 years of age), minors may not enroll in research without their parent’s documented permission, unless a waiver has been granted to the researcher in writing by the Grand Valley State University Institutional Review Board. Minors between 7 and 17 years of age are required to assent to participation. Documentation of minors’ assent is permitted, but is not required. Minors under age 7 are not required to assent to participate. For more information, see**  [**IRB Policy 812: Informed assent and parental permission**](https://www.gvsu.edu/cms4/asset/F51281F0-00AF-E25A-5BF632E8D4A243C7/policy_812_effective_05-01-2018.pdf)**. The researcher will need to modify the Agreement to Participate text accordingly, depending upon the target participant population.**

1. **CONTACT INFORMATION** State “If you have any questions about the study you may contact

 NAME: PHONE:

 E-MAIL:

If you have any questions about your rights as a research participant, please contact the **Office of Research Compliance & Integrity** at Grand Valley State University, 1 Campus Drive, Allendale, MI. Phone: 616-331-3197. E-mail: rci@gvsu.edu.

This study has been approved by the Institutional Review Board at Grand Valley State University (Protocol #XX-XXX-H).”

**Assessment of grade-level readability in Microsoft Word:** Within Word, go to FILE, choose Options, and then select Proofing. Click the box labeled “Readability Statistics” and click OK. Go to the REVIEW tab and select Spelling & Grammar. Readability stats, including the Flesch-Kincaid Grade Level estimate, will now be included with the spelling and grammar report.

If you have any questions about how to use this consent template, please contact the Office of Research Compliance and Integrity at (616) 331-3197 or rci@gvsu.edu. The office observes all university holidays. Please include your study title and reference number in all correspondence with our office.