

**Guidelines for Constructing an Informed Consent Document**

***\*\*Use this template for EXEMPT protocols that are also 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.***

*Use GVSU letterhead. Include all of the information indicated below as appropriate to the study. All information below is required to be included. 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).*

1. **TITLE** Research Study Title
2. **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.
3. **PURPOSE** Clearly indicate it is a research study and state the purpose of the study.

# PROCEDURES

* + 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** Describe the known risks to participants from participating in the research itself, if any. 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.”
2. **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.
3. **POTENTIAL BENEFITS TO SOCIETY** Describe the anticipated direct or indirect benefits to society from completion of the study and dissemination of results, in any. Do not exaggerate the potential for benefit.
4. **VOLUNTARY PARTICIPATION** State “Your participation in this research study is completely voluntary. You do not have to participate. You may quit at any time without any penalty to you.”
5. **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.”
6. **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.”
7. **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.”
8. **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.”
9. **DATA RETENTION** State “Personal data will be retained for [insert period of time] following the completion of this research.”
10. **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. **AGREEMENT TO PARTICIPATE**  By checking the consent box 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.

🞎 I give my consent to participate in this research project.

**Note: Names and signatures should NOT be collected during the consent process for exempt studies, unless you need that information to successfully conduct your research project or an additional regulation (such as HIPAA) that requires signed and dated consent applies to your study. Note that the GDPR does not require signed consent.**

1. **CONTACT INFORMATION**  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, or concerns or complaints about the research or research team members, 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 reviewed 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.