



Guidelines for Constructing an Informed Consent Document

*Use GVSU letterhead. Include all of the information indicated below as appropriate to the study. Use the numbered headings indicated in **BOLD RED CAPS**. For most sections the information should be expressed in a few simple sentences, **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** State the purpose of the research study
4. **REASON FOR INVITATION** State the reason for inviting individuals to participate
5. **HOW PARTICIPANTS WILL BE SELECTED**
 - Basis of selection into the study, if any.
 - Basis for exclusion from the study, if any. If none, omit mention of exclusions.
6. **PROCEDURES**
 - Briefly describe all procedures participants will perform, and their location.
 - State approximate time required for each procedure.
 - Specify all out of pocket costs to participants, if any. If none, state none.
7. **RISKS** 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 no risks are anticipated, state “We do not think there is any risk to you from participating in this research.”
8. **COMPENSATION FOR HARM** State “If you are harmed from participating in this research 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 (Compensation for Harm) if there are no anticipated harms from participating in the research.**
9. **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.
10. **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.

11. **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.”
12. **PRIVACY AND CONFIDENTIALITY** State “Your name will not be given to anyone other than the research team. All the information collected from you or about you 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.”
13. **RESEARCH STUDY RESULTS** State “If you wish to learn about the results of this research study you may request that information by contacting:” _____.
14. **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, state “There will be no payment for participation in the research.”**
15. **AGREEMENT TO PARTICIPATE** In studies enrolling adult participants only, state “By signing this consent form below you are stating 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 may ask more questions or quit participating at any time without penalty.

_____ (Initial here) I have been given a copy of this document for my records.

Print Name: _____

Sign Name in ink: _____

Date Signed: _____”

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 Human Research Review Committee. Minors between 7 and 18 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 [HRRC Policy 812: Informed assent and parental permission](#). The researcher will need to modify the Agreement to Participate text accordingly, depending upon the target participant population.

16. State “If you have any questions about this study you may contact the lead researcher as follows:
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.”

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, please contact the Office of Research Compliance and Integrity at (616) 331-3197 or rci@gvsu.edu. The office observes all university holidays, and does not process applications during exam week or between academic terms. Please include your study title and reference number in all correspondence with our office.