

Adult Informed Consent Template
**CONSENT COMPONENTS FOR EXPERIMENTAL PROCEDURE/ RESEARCH
STUDY:**

1. Title of the research project

Provide title.

2. Names of the researchers

Provide names, university affiliation, and degrees.

3. Description of the research

Discuss in lay terms the scientific question to be answered, its significance, and expected outcomes.

4. Description of human subject involvement

Discuss in lay terms what will be required of the subject during his/her participation. Include a description of the research procedures and identification of any procedures which are experimental.

5. Length of human subject participation

For each subject, provide a reasonable estimate of the duration of each session, number of sessions, and total duration of participation across the project.

6. Risks & discomforts of participation

Provide a detailed description, in lay terms, of the risks & discomforts of participating in the study. If the study poses no more than minimal risk, provide the subject with an explanation of why and how the research meets the definition of minimal risk. Provide information about other appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.

If minimal risk, **suggested text:** *"This project is deemed as no more than minimal risk. The study team does not foresee or anticipate any direct risk to the subjects."*

7. Measures to be taken to minimize risks and discomforts

Please describe in lay terms any measures taken to minimize risk and discomfort of the subject during his/her participation in the research study.

8. Expected benefits to subjects or to others

Provide information on the probability of direct benefits, if any. Indicate clearly if no benefit is likely.

Suggested text: *"Although you may not receive direct benefit from your participation, others may ultimately benefit from the knowledge obtained in this study."*

9. Costs to subject resulting from participation in the study

Indicate who will bear the costs of the study. Inform the subject of any financial burden on them or their insurance carrier, of the probability of nonpayment by their carrier, and of any costs above those of customary treatments (if applicable).

10. Incentives to subject for participation in the study

Provide information on financial incentives or reimbursement of expenses. Indicate on the consent document if full payment is given if the subject withdraws from participation in the research study.

11. Confidentiality of records/data

Include a statement describing the extent to which confidentiality of records identifying the subject will be maintained.

- a) Describe eventual disposition of identifiable information, tapes, questionnaires, etc.
- b) Describe any legal duty to report abuse that might supersede confidentiality promises.

***Suggested text:** "You will not be identified in any reports on this study. Records will be kept confidential to the extent provided by federal, state, and local law. However, the Institutional Review Board, the sponsor of the study (i.e. NIH, FDA, etc.), or university and government officials responsible for monitoring this study may inspect these records."*

12. Management of Physical Injury (include only if applicable)

No written informed consent may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

***Suggested text:** "In the unlikely event of physical injury resulting from research procedures, the University will provide first aid medical treatment or emergency care. Additional medical care will be provided if the University determines that it is responsible to provide such treatment. By signing this form, you do not give up your right to seek additional compensation if you are harmed as a result of participation in this study."*

13. Availability of further information (include only if applicable)

***Suggested text:** "If significant new knowledge is obtained during the course of this research which may relate to your willingness to continue participation, you will be informed of this knowledge."*

14. Contact Information

The name, academic title, and telephone number of the investigator should appear on the consent form. If a researcher is a university student, the name and telephone number of the faculty advisor must also be provided.

15. Required IRB Contact Information

Include the following information in a separate paragraph after the principal investigator contact information:

***Suggested text:** "Should you have questions regarding your rights as a research participant, or wish to obtain information, ask questions, or discuss with someone other than the researcher(s), please contact Mary Mandeville in the Institutional Review Board, 530 French Hall, Flint, MI., 48502, 810-762-3383, (For International Studies: US Country Code: 001) email: irb-flint@umflint.edu."*

16. Voluntary nature of participation

***Suggested text:** "Your participation in this project is voluntary. Even after you sign the informed consent document, you may decide to leave the study at any time without penalty or loss of benefits to which you may otherwise be entitled."*

Additional text to include if applicable:

1. Alternative Therapies
"Alternative forms of treatment may be available in the event you do not wish to participate in the proposed study" (Provide an explanation of the alternative therapies available to the subject).
2. Survey Research
"You may skip or refuse to answer any survey question without affecting your study compensation or academic standing/record."

17. Documentation of the consent (A copy MUST be provided to the subject)

***Suggested text:** "One copy of this document will be kept together with the research records of this study. Also, you will be given a copy to keep."*

You may also wish to insert language about additional copies that may be kept, if applicable.

18. Consent of the subject:

***Suggested text:** "I have read [or been informed] of the information given above. [Insert Name of Investigator or Designated Representative here] has offered to answer any questions I may have concerning the study. I hereby consent to participate in the study."*

NOTE: A signature of a parent or a guardian is required for a minor. A minor, in the State of Michigan, is a person under the age of 18 years.

