Adult Informed Consent Template
HUM# (from eResearch)

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. **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."

6. **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.

7. **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 risk greater than that encountered in your routine daily activities."*

   Suggested text for alternative treatment*: "There may be other ways of treating your condition if you don't wish to be in this research study. Check with your health care provider to discuss other options. "*

8. **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.

9. **Expected benefits to subjects or to others**
   Provide information on the probability of direct benefits, if any. Indicate clearly if no benefit is likely. (Incentive payments are not considered a benefit.)

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

10. **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).

11. **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.

12. **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 (if applicable, i.e. NIH, FDA, etc.), or university and government officials responsible for monitoring this study may inspect these records."*

13. **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: *"Please tell the researchers if you have any injuries or other problems related to your participation in the study. The University may be able to assist you with obtaining emergency treatment, if appropriate, but you or your insurance company will be responsible for the cost. By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study."*

Include this section only if you will collect biospecimens.

14. **<u>Collection of identifiable private information or identifiable biospecimens.</u>**
    If your study will involve the collection of identifiable private information or identifiable biospecimens, you must include a statement indicating whether:

    - identifiers may be removed, and
    - de-identified information or biospecimens may or may not be used or shared for future research

Use of biospecimens. Include a statement indicating whether:
Biospecimens may be used for commercial profit, and
The subject will share in that profit

Clinically relevant results. Include a statement indicating whether the clinical results, including individual research results, will be returned to the subject, and if so, under what conditions

Whole genome sequencing. Include a statement that the research will or might include whole genome sequencing.

*If applicable

15. **Availability of further information**

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."*

16. **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.

17. **Required IRB Contact Information (Include only if IRB reviews the project. If the project is self-determined do not include this section.)**
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 the Institutional Review Board, 4204 William S White Bldg., Flint, MI., 48502, 810-762-3383, (For International Studies: US Country Code: 001)*
email: irb-flint@umflint.edu."

18. **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.

19. **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.

ADULT SUBJECT OF RESEARCH

_____

Printed Name Consenting signature date

LEGAL REPRESENTATIVE (If Applicable)

_____

Printed Name Consenting signature date

Relationship to Subject: _____

20. **Audio/Video Recording of subjects** (*Include if applicable)*
Include a statement that audio and/or video recording devices will be used, if applicable. You must also state what will be done with the recordings/pictures upon completion of the study (destroyed, erased, archived, kept for future studies, etc.). Please provide a separate line on the consent form for the subjects to agree to each audio/video session to be photographed or recorded. For example:
Please sign below if you are willing to have this interview recorded (specify audio or video).

_____

Signature Date

I do not wish to have my interview recorded, however wish to participate in the research project.

_____

Signature Date