INSTITUTIONAL REVIEW BOARD

GUIDELINES FOR CREATING THE INFORMED CONSENT FORM

The following template is for use when creating the consent form to relay information about your study to participants. Please insert the details that are specific to your study. Below are additional tips for creating your informed consent form:

- Keep the language simple. Consent forms should be written at a 6th to 8th grade reading level or below. Avoid use of technical terms. When using acronyms or abbreviations, spell out the full meaning the first time they are used.

- Compose the consent form to speak to the participants, not about them. For example, "You will be asked to…" instead of "The participant will be asked to…"

- The title of the study on the consent form need not match the title of the study in the project outline form. Sometimes it is warranted to use a simpler title for the consent form.

- Most sections are required. However, you may remove the compensation section if no compensation is offered to participants. You may remove the Statement on Future Use of Identifiable Data section if your research is not collecting identifiable private information/biospecimens. You may remove the section on alternative procedures if there are none.

- If you are a student, indicate that by giving your name and contact information as well as your advisor's contact information in the appropriate contact information section.

- Include a version date at the very end of the consent form. If revisions are requested by the board, update the version date when requested revisions are made.

Informed Consent Template:

TITLE OF THIS STUDY *[Provide a title for your research project]*

[Fill out this information if you are NOT a student researcher]:

Principal Investigator: *[Provide your name, your university affiliation and your degree.]*

Co-investigator: *[Provide the name, university affiliation and degree of any and all co-investigators.]*

Study Sponsor: *[Provide the names of any all study sponsors.]*

[Fill out this section if you ARE a student researcher]:

Principal Investigator: *[Provide your name, your university affiliation and your degree.]*

Co-investigator: *[Provide the name, university affiliation and degree of any and all co-investigators.]*

Faculty Advisor: *[Provide the name, university affiliation and degree of your faculty advisor.]*

Study Sponsor: *[If applicable, provide the names of any all study sponsors.]*

Invitation to be Part of a Research Study

1. **Description of the research study and your involvement:** *[Provide a brief paragraph summary of the important information potential study participants will need to know to make an informed decision about whether they wish to be a participant in this research.*

   This paragraph should include:

   - *The purpose of the study.*
   - *What will be required of the volunteer?*
   - *How long will it take to be a research participant?*
   - *What are the anticipated risks or discomforts associated with being involved in this study?*
   - *What are the benefits of participating in this study?*
   - *Is taking part in this research project voluntary?*
   - *Can the participant stop at any time?*
   - *Are there any appropriate alternative procedures or courses of treatment that might be advantageous to the volunteer? If so, explain.]*

     Suggested text for this paragraph: "The purpose of this study is to… It will require …"

2. **The voluntary nature of your involvement and the length of your participation in this study.** *[Provide details about the voluntary nature of the study. And give a reasonable estimate of the amount of time the volunteer will be involved in the research. Please also include the estimated total number of participants.]*

   Suggested text for beginning this paragraph: "Your participation in this study is entirely voluntary. Even after you sign this informed consent form, you may decide to leave the study at any time without a penalty or loss of benefits to which you might be entitled…It is estimated that you would be involved in this study for… Approximately [number] participants will be enrolled in the study."

3. **Risks and discomforts of your participation in this research project.** *[Provide a detailed description, in easy-to-read terms, of the risks and discomforts that may be associated with participating in the study. If the study poses no more than minimal risk, give the potential subject an explanation of why and how the research meets the definition of minimal risk. If there is a risk greater than minimal, then spell out in detail what those risks are.]*

   Suggested text for beginning this paragraph if there is only minimal risk: "This project is unlikely to have 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 beginning this paragraph if there is greater than minimal risk: "The researchers have determined that there may be risks in being part of this study. Those risks include…"

4. **Measures that will be taken to minimize the risks and discomforts to you.** *[Describe in terms a lay person will be able to understand what measures will be taken by the researcher to minimize risk and discomfort of the subject during his/her participation in the research study.]*

   Suggested text for beginning this paragraph: "The researcher has…

5. **Expected benefits of this study to you or to others.** *[Provide information on the probability of direct benefits, if any, to anyone participating in this research. Indicate clearly if no benefit is likely. Any incentive payments or compensation to participants are not considered a benefit and will be dealt with below.]*

   Suggested text for beginning this paragraph if there is no particular benefits expected: "Although you may not receive direct benefit from your participation, others may ultimately benefit from the knowledge obtained in this study."

   Suggested text for beginning this paragraph if there are some particular benefits that may occur: "Some people who are part of this study may receive the benefit of…"

6. **Costs to you resulting from participation in this study.** (if applicable) *[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.]*

   Suggested text for this paragraph if there is no particular expense for the participants: "This study is paid for by…and, therefore, there will be no cost to you aside from your time to…"

   Suggested text for this paragraph if there is some cost to participants: "It is expected that you will be responsible for…"

7. **Compensation to you for being part of this study.** *[Provide information on financial incentives, compensation, or reimbursement of expenses. Indicate whether full payment is given if the subject withdraws from participation in the research study.]*

   Suggested text for this paragraph if there is no incentive or compensation: "If you are part of this study, you will receive no compensation or payment."

   Suggested text for this paragraph if there is an incentive or compensation: "If you are a part of this study, you will be eligible to receive…Even if you do not complete this study, you will…"

8. **Alternative procedures or courses of treatment**. *[Disclose any alternative procedures that might be advantageous to the volunteer were they carried out in place of the planned research procedure. If there is an alternative procedure that might be advantageous to the volunteer, indicate clearly why the proposed procedure is being used.]*

   Suggested text for this paragraph: "There may be other ways of treating your condition if you don't wish to be in this research study. For instance. . . You might also check with your health care provider to discuss other options."

9. **Confidentiality of your records or the data you provide while being part of this study:** *[Include a statement describing the extent to which confidentiality of records identifying the subject will be maintained. You should a) describe eventual disposition of identifiable information, tapes, questionnaires, etc. and you should b) describe any legal duty to report abuse that might supersede confidentiality promises.]*

   Suggested text for this paragraph: "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."

10. **Management of physical injury to you.** (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 for this paragraph: "Please tell the researchers if you have any injuries or other problems related to your participation in this 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."

11. **Collection of identifiable private information or identifiable biospecimens.** (if applicable) *[If your study will involve the collection of identifiable private information or identifiable biospecimens, you must include a statement indicating whether a) identifiers may be removed, and b) de-identified information or biospecimens may or may not be used or shared for future research.*

    Furthermore, if this study involves the use of biospecimens, you must include a statement indicating whether a) biospecimens may be used for commercial profit, and b) the subject will share in that profit.]

    Suggested text for this paragraph: "Since this study will collect…from you, you should be aware that…will (or will not) be used for commercial profit and you will (or will not) be able to share in that profit."

    [Also, include a statement indicating whether the clinical results, including individual research results, will be returned to the subject, and if so, under what conditions.]

    Suggested text for this paragraph: "The clinical results from this study that apply to you will (or will not) be returned to you after the study is completed…"

    [Finally, if the study involves whole genome sequencing, provide a statement indicating that the research will or might include whole genome sequencing.]

    Suggested text for this paragraph: "This research study will include whole genome sequencing. This means that…"

12. **Notification of further information.** *[Provide information about notification if new knowledge is gained in the study that might affect an individual's continued involvement in the study.]*

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

13. **Contact information.** *[The name, academic title, and telephone number of the investigator should appear on this consent form. If one or more of the researchers are university students, the name and telephone number of the faculty advisor must also be provided.]*

14. **Required IRB contact information.** *[Include the name, address, phone number and email address of the head of the University's Institutional Review Board.*

    Suggested text for this information: "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 at: IRB@udmercy.edu."

15. **Documentation of this consent form.** *[A copy of this informed consent form must be provided to the subject.]*

    Suggested text for this paragraph: "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."

16. **Your consent to be part of this study.** *[Include a statement showing that the subject has been informed about the study and has had an opportunity to answer questions about the research project.]*

    Suggested text for this paragraph: "I have read (or been informed) of the information given above. (Insert the name of the investigator or principal researcher here) has offered to answer any questions I have concerning the study. I agree and give my consent to be a part of this 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: _____

17. **Audio/Video Recording or photographs of subjects involved in this study:** *(if applicable) [If there is to be audio or video recording or photographs used in this research project, **i**nclude a statement that audio and/or video recording devices and/or photographs will be used. You must also state what will be done with the recordings/photos upon completion of the study; that may mean that these materials will be destroyed, erased, archived, kept for future studies, etc. Provide a separate line on this consent form for the subject to agree to each audio/video session to recorded or for each photograph to be taken.]*

Suggested text for this paragraph:

"Please sign below if you are willing to have this interview recorded by (specify audio or video) or photographed (if applicable)."

_____ _____

Signature Date

"I do not wish to have my interview recorded (or photographed), however, I wish to be involved in this research project.

_____ _____

Signature Date