The following instructions and examples are provided to assist in development of the Adult Participant Biomedical Consent Form. Before submitting the consent document for IRB approval, delete all comments/instructions in red or non-applicable language.

Subject Consent to Take Part in a Study of
(**Insert Title of Study**)
University of the Incarnate Word
(If other institutions are engaged in the research, list their name(s))

Authorized Study Personnel: (Name, Academic Degree, Position)
(UIW Department or School)
(Phone)
(email) (Provide this information for each investigator)

IMPORTANT NOTE: Regulations now require informed consent documents to contain a concise and focused presentation of the key information that is most likely to help potential subjects understand why they might or might not want to participate in the study. A template for the Key Information section is provided below. Many studies have brief consent documents (1-3 pages) that meet this new requirement *without the need for a separate key information section.* If your informed consent document is relatively brief, a separate Key Information section is not needed. However, if your project is complex or involves numerous procedures, this summary is required.

Key Information: Your consent is being sought for a research study. The purpose of the research is to (briefly describe purpose). If you agree to participate in this study, the project will involve:

- Procedures will include (provide **brief** summary of procedures)
- (X) number of visits are required
- These visits will take a (X) amount of hours total
- There are OR are not risks associated with this study: (**briefly** describe risks)
- You will be paid (X) amount for your participation OR You will not be paid for your participation
- Your participation is voluntary and you may decide not to participate at any time

(If there is any other information that is most likely to assist the prospective subjects in understanding why they might or might not want to participate, describe it **concisely** here with additional bullets.)

Invitation: You are invited to volunteer as one of ## subjects in the research project named above. The information in this form is meant to help you decide whether or not to participate. If you have any questions, please ask.

Why are you being asked to be in this research study? You are being asked to be in this study because (Explain **succinctly** why the individual is eligible to participate. Major eligibility criteria may be included in this section. Exclusions, such as exclusions for pregnant or breast feeding women, should be listed here as well.)

(Note: If the study involves deception or incomplete disclosure which necessitates a debriefing process, a general statement may be added here that more information will be given to subjects at the conclusion

of the study, e.g., "At the end of the study, we will explain in greater detail what we hope to learn from this research." If the investigator believes that such a statement would bias study results, he/she should discuss this in the protocol as part of the justification for use of deception or incomplete disclosure.)

What is the reason for doing this research study? The purpose of this study is to (Use **layperson** terms to **briefly** describe the scientific purpose of the study.)

What will be done during this research study? (Use **concise**, **simple** terms to describe what the subject will be asked to do and how long the procedure(s) will take. If appropriate, identify any procedures that are experimental.)

(If necessary, include the following precaution for female subjects.)
Precautions for Female Subjects: If you are female, we will administer a urine pregnancy test prior to the procedure(s). If the test shows that you might be pregnant, you will not undergo the procedure(s) and may be excluded from the study.

(If the research is conducted concurrently with standard of care, include one of the following statements.)
If you take part in this study, the main difference between your regular care and the study is (describe).

OR

This study is not part of your health care.

How will my data/samples/images be used? (If none of the circumstances described below apply to the research project, this section may be omitted.)

(If the research involves the collection of identifiable private information or identifiable biospecimens, include one of the following statements regarding the possible future use of the data or samples.) Your (specific data or samples) could be used for future research studies. You are given the option to choose whether you will allow your deidentified (data or samples) to be stored indefinitely for further analysis or other relevant research studies. (Tweak the data sharing language as needed to fit your study – for example, if you might share data that potentially could be identifiable, such as videotapes, then you should make that clear.)

OR

Your (specific data or samples) will not be used or distributed for future research studies, even if identifiers are removed. Your (data or samples) will be destroyed within (X) year(s) after the completion of this study.

(If the research involves biospecimens, include the following statement regarding whether the biospecimens may be used for commercial profit and whether the subject will or will not share in the commercial profit.) Your (specific samples) (may or may not) be used for commercial profit and you will not share in any of the commercial profit from the use of your (specific samples).

(If the research involves biospecimens, include the following statement regarding whether the research will or might include whole genomic sequencing.) Your (specific samples) collected for this research will be analyzed for the study. As part of the analysis the research (will or might) include genomic sequencing.

This means that the researchers (will or might) look at your sample to learn about your genes (DNA) in order to understand (describe purpose of genomic sequencing).

OR

Analysis of your (specific samples) that are collected for this research will not include genomic sequencing. This means that the researchers have no plans to look at the sample to learn about your genes (DNA).

Will I be notified if my data/samples/images result(s) in an unexpected finding? (If the study may collect clinically relevant data/samples/images, include one of the following statements regarding whether or not clinically relevant research results, including individual research results, will be disclosed to subjects. **If the study will not collect clinically relevant data/samples/images, this section may be omitted.**)

(If no clinically relevant research results will be shared, include the following statement.) When (specific data/samples/images) are collected and analyzed, there is a chance of finding something unexpected. There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as feeling worried about a finding for which no treatment is needed).

The results from the (data/samples/images) we collect in this research are not the same as what you would receive as part of your health care. The (data/samples/images) are not reviewed by a physician who normally reads such results. Due to this, you will not be informed of any unexpected findings. The results of your (data/samples/images) will not be placed in your medical record. If you believe you are having symptoms that may require care, you should contact your primary care physician.

(If clinically relevant research results will be shared, include the following statement.) When (specific data/samples/images) are collected and analyzed, there is a chance of finding something unexpected. There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as feeling worried about a finding for which no treatment is needed).

In this study, you will be informed of any unexpected findings of possible clinical significance that may be discovered during review of results from your (data/samples/images). The results from the (data/samples/images) we collect in this research are not the same as what you would receive as part of your health care. The (data/samples/images) will be reviewed by a physician who normally reads such results and they will inform us if there are any unexpected findings and we will provide you with this information so that you may discuss it with your primary care physician. If you believe you are having symptoms that may require care prior to receiving any information from this study, you should contact your primary care physician.

What are the possible risks of being in this study? (Identify each intervention with a subheading and then state the associated risk(s) using **simplistic** language, along with their frequency and severity. The most serious and common risks should be addressed first, followed by the less common and serious risks. Describe what will be done to minimize risks.) (Conclude with) It is possible that there could be other risks that cannot be known in advance.

(If there are no known risks, include the following statement.) There are no known risks to you from being in this research study.

What are the possible benefits to you? (If direct subject benefits are anticipated, describe the possible benefits.) (Conclude with) However, you may not receive any benefits from being in this research study.

(If direct subject benefits are not anticipated, state the following.) You are not expected to receive any benefits from being in this study.

What are the possible benefits to other people? (State the possible benefits to science and/or society.) The benefits to science and/or society may include…

What are the alternatives to being in this research study? (Describe appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject OR) Instead of being in this research study you can choose not to participate.

What will being in this research study cost you? (State any costs to the subject that may result from participation in the research OR) There is no cost to you to be in this research study.

Will you be compensated for being in this research study? (If the subject will be compensated for participation, state the amount of compensation and conditions for payment. A prorated payment system should be used when appropriate and commensurate with the degree of participation required. If there will be no compensation state) You will not be paid for your participation in this research study.

How will information about you be protected? Everything we learn about you in the study will be confidential. The only persons who will have access to your research records are the study personnel, the Institutional Review Board (IRB), and any other person, agency, or sponsor as required by law. If we publish with results of the study, you will not be identified in any way.

(If the research requires collection of sensitive information, follow the above with a **brief** description of the precautions to be used to protect the data. Examples are provided below.)

(For projects that collect paper records) The data will be stored in a locked cabinet in the principal investigator's office and will only be seen by the research team during the study and for X years after the study is complete.
(For projects that collect electronic records) The data will be stored electronically on a secure server and will only be seen by the research team during the study and for X years after the study is complete.

What will happen if you decide not to be in this research study or decide to stop participating once you start? You can decide not to be in this research study, or you can stop being in this research study at any time, for any reason. Deciding not to be in this research study or deciding to withdraw will not affect your relationship with the investigator or with the University of the Incarnate Word (list other institutions if applicable). You will not lose any benefits to which you are entitled.

(For studies enrolling UIW students add) Deciding not to be in the study or deciding to withdraw will not affect your class standing or grades at the University of the Incarnate Word. (In addition to IRB approval, you may be required to seek permission from the appropriate campus administrator.)

(For studies enrolling UIW employees add) Your participation in this research is in no way part of your university duties, and your refusal to participate will not in any way affect your employment with the

university, or the benefits, privileges, or opportunities associated with your employment at the University of the Incarnate Word. (In addition to IRB approval you may be required to see permission from the employee's supervisor.)

(If applicable, state the following.) If the researchers get any new information during this research study that may affect whether you would want to continue being in the study you will be informed promptly. The researchers may also make the decision to remove you from the study, if:

- Your health changes and being in the study is no longer in your best interest;
- You do not follow the study protocol or no longer meet the requirements to be in the study; and/or
- The study is stopped by the sponsor, IRB or researchers.

(If the project utilizes a specific research treatment, state the following) For your safety, please talk to the researchers before you stop any research treatments. They will advise you on how to stop the treatment safely.

What should you do if you have a problem or question during this research study? If you have a problem as a direct result of being in this study, you should immediately contact one of the people listed at the beginning of this consent form.

(You may also provide information on resources to participants dependent on the project and level of risk. For example, you may provide them with student health or wellness contact information. For research involving more than minimal risk, an explanation as to whether any medical treatments are available if injury occurs must be included and, if so, what they consist of, or where further information may be obtained.)

If you have any questions now, feel free to ask us. If you have additional questions about your rights or wish to report a problem that may be related to the study, please contact the University of the Incarnate Word Institutional Review Board office at 210-805-3036 or 210-805-3565.

Optional Study Elements

(This section should include other explicit consents for optional elements of the research procedures, such as contacting participants again in the future about participation in other research studies.)

Examples:

Consent for future use of data

Initial one of the following to indicate your choice:

_____I give permission for my deidentified (data or samples) to be used in the future for additional analysis or other relevant research studies. I understand that no additional informed consent for this use will be sought. I understand that my deidentified (data or samples) can be stored indefinitely.

_____I give my permission for my (data or samples) to be used for this research study only. I do not give permission for any future use beyond the scope of this research study. I understand that my (data or samples) will be destroyed within (X) year(s) after completion of this study.

Consent for use of contact information to be contacted about participation in other studies

Initial one of the following to indicate your choice:

_____I agree to allow the researchers to use my contact information collected during this study to contact me about participating in future research studies.

_____I do not agree to allow the researchers to use my contact information collected during this study to contact me about participating in future research studies.

Consent

Your signature indicates that you (1) consent to take part in this research study, (2) that you have read and understand the information given above, and (3) that the information above was explained to you, and you have been given the chance to discuss it and ask questions. You will be given a copy of this consent form to keep.

_____
Name of Participant

_____ _____
Signature of Participant Date

_____
Name of Principal Investigator/Designee

_____ _____
Signature of Principal Investigator/Designee Date

IF YOU ARE SEEKING A WAIVER OF DOCUMENTED (SIGNED) CONSENT, DELETE THE LINES ABOVE FOR THE PARTICIPANT'S NAME AND DATED SIGNATURE and substitute instead the wording "If you agree to participate, please say so. You will be given a copy of this form to keep for your records."