**Informed Consent**

No investigator may involve a human being as a subject in research covered by these policies unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative.

**(See attached Informed Consent template)**

**The Informed Consent will contain:**

1. A statement that the study involves research;

2. An explanation of the purpose of the research, an invitation to participate and explanation of why the participant was selected, and the expected duration of the participant's participation;

3. A description of procedures to be followed and identification of which procedures are investigational and which might be provided as standard care to the participant in another setting. Use of research methods such as randomization and placebo controls should be explained;

4. A description of any foreseeable risks or discomforts to the participant, an estimate of their likelihood, and a description of what steps will be taken to prevent or minimize them; as well as acknowledgment of potentially unforeseeable risks;

5. A description of any benefits to the participant or to others that may reasonably be expected from the research, and an estimate of their likelihood;

6. A disclosure of any appropriate alternative procedures or courses of treatment that might be advantageous to the participant;

7. A statement describing to what extent records will be kept confidential, including examples of who may have access to research records such as hospital personnel, the FDA, and drug sponsors;

8. For research involving more than minimal risk, an explanation and description of any compensation and any medical treatments that are available if participants are injured through participation; where further information can be obtained, and whom to contact in the event of research-related injury;

9. An explanation of whom to contact for answers to questions about the research and the research participant's rights including the name and phone number of the Principal Investigator (PI);

10. A statement informing the subject that inquiries regarding the nature of the research, his/her rights s a subject, or any other aspect of the research as it relates to his/her participation as a subject can be directed to the Research Integrity Officer at Eastern Nazarene College;

11. A statement that research is voluntary and that refusal to participate or a decision to withdraw at any time will involve no penalty or loss of benefits to which the participant is otherwise entitled;

12. A statement that if a participant declines to continue, any data gathered to that point may be part of data analysis;

13. A statement indicating that the participant is making a decision whether or not to participate, and that his/her signature indicates that he/she has decided to participate having read and discussed the information presented;

14. A statement outlining the nature of subject remuneration (if any). Remuneration should be described as a “token of appreciation” for participating subjects. Care should be taken to ensure that remuneration is appropriate to the scope and context of the project. Excessive remuneration may be viewed as potentially coercive;

15. Authorization for Use of Private Health Information - if personal information considered

“Protected Health Information” is used in the study;

16. Informed consent should be on ENC letterhead.

**Additional Elements of Informed Consent**

When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus) if the subject is or may become pregnant which are currently unforeseeable;

2. anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent;

3. any additional costs to the subject that may result from participation in the research;

4. the consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject;

5. a statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation will be provided to the subject; and

6. the approximate number of subjects involved in the study (§ 45 CFR 46.116).

**Documentation of Informed Consent**

1. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

a. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; or

b. that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

2. Except as provided in paragraph 1 above, informed consent shall be documented by the use of a written consent form approved by the IRB or by use of an electronic consent form for electronic surveys (see IRB webpage). The written consent forms must be signed by the subject or the subject’s legally authorized representative. A copy shall be given to the person signing the form.

3. Except as provided in paragraph 1 of this section, the consent form may be either of the following:

a. A written consent document that embodies the elements of informed consent

required by §45 CFR 46.116 above. This form may be read to the subject or the subject’s legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

b. A short written consent document stating that the elements of informed consent required by §45 CFR 46.116 have been presented orally to the subject or the subject’s legally authorized representative. When this method is used, there shall be a witness to the oral presentation. See §45 CFR 46.117 for additional related regulations.

**Parental Consent Form**

The IRB shall determine that adequate provisions are made for soliciting the parental consent for minors participating in research.



[List Project Title]

[List Researchers Involved]

[List IRB # once assigned]

**INFORMED CONSENT**

**(This is a template to be customized for your research)**

**Voluntary Status:** You are being invited to participate in a research study conducted by the researchers listed above. You are being asked to volunteer since you meet the requirements for

enrollment into this study. Your participation is voluntary which means you can choose whether

or not you want to participate. You may withdraw any time without penalty. If you decline to

continue, any data gathered to that point may be used in data analysis. If you choose not to

participate, there will be no loss of benefits to which you are entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being

in this study, and what you will have to do in this study. The research team is going to talk to you

about the study, and they will give you this consent form to read. You may also decide to discuss

it with your family or friends. If you find some of the language difficult to understand, please ask

the researcher and/or the research team about this form. If you decide to participate, you will be asked to sign this form.

**Purpose:** The study for which you are being asked to participate is designed to **…[*insert 3 to 5 sentences about the study]***

**Procedure:** To be a voluntary participant in this study, you will be asked to…[***insert brief procedure for the study].***

***Include if applicable*** ð The study asks that you grant the researchers permission to view your

medical or clinical record. You should know that the researchers will copy the information from your chart, but not include your name or any other identifying information such as your medical record number, birth date or social security number. You will also be asked to sign a separate form that specifically addresses using your protected health information (PHI) for the purposes of research.

**Commitment and Compensation:** Your total participation in the study will take approximately

[ ] days or hours over [ ] sessions. Each session will last approximately [ ] minutes or hours.

***Include if applicable***  As a token of our appreciation for your participation in this project, you

will receive an honorarium of $\_\_\_. **OR** You will not receive financial compensation for participation in the study OR you will receive pizza..

**Possible Risks & Benefits:** It is expected that participation in this study will provide you with no more than minimal risk or discomfort which means that you should not experience it as any

more troubling than your normal daily life. However, there is always the chance that there are

some unexpected risks. The foreseeable risks in this study include an accidental disclosure of

your private information, or discomfort by answering questions that are embarrassing. If you feel uncomfortable or distressed, please tell the researcher and he/she will ask you if you want to continue. Because this is research and does not have anything to do with the current services you are receiving, you can withdraw from the study at any time without penalty. You will not receive any direct benefits from participating in this study; however, your participation in this study will help improve the knowledge about [list expected outcomes in the study]. Your participation may also benefit other people with similar concerns.

**Confidentiality & Consent:** The investigator and staff involved with the study will keep your

personal information collected for the study strictly confidential. Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Your identity will be kept strictly confidential by [describe coding procedures and plans to safeguard data]. [Explain how the data will be stored, handled, etc.] [Disclose those parties that could potentially have access to the research data.]

This document explains your rights as a research subject. If you have questions regarding your participation in this research study or have any questions about your rights as a research subject, please contact the Principal Investigator using the information at the bottom of this form. Concerning your rights or treatment as a research subject, you may contact the Research Integrity Officer via Office of the Provost at Eastern Nazarene College (ENC) at (617) 745-3000.

**New Information:** During the course of this study, we may discover information that could be

important to you. This includes information that, once learned, might cause you to change your

mind about being in the study. We will notify you as soon as possible if such information becomes available.

**Injury: *(For biomedical research, please include this section)*** If you have a medical emergency

during the study you may contact the Principal Investigator at the bottom of this form. You may

also contact your own doctor, or seek treatment outside of the [list study setting]. Be sure to tell the doctor or his/her staff that you are in a research study being conducted at [list study setting]

in collaboration with APU. Ask them to call the telephone numbers at the bottom of this consent form for further instructions or information about your care.

In the event of any physical injury resulting from research procedures, you will not be provided medical treatment through Azusa Pacific University, however, you may seek treatment with your primary care physician or [if research is conducted at a hospital list hospital – make sure and coordinate this aspect of the consent with your site supervisor]. APU will not provide you with financial compensation if you are injured in this study.

**Conflict of Interest:** The Principal Investigator has complied with the Eastern Nazarene College

Conflict of Interest section of the IRB policy

**[FOR TREATMENT STUDIES ONLY] Treatment Choices:** There are alternative treatments available to you, including [list alternative treatments and where they may be received]. If you agree to participate in this treatment study, you will be given an opportunity to discuss alternative treatments with the researcher or [another professional].If you choose not to participate in this study, or choose to withdraw from the study, the researcher will refer you to someone who will discuss treatment alternatives for your condition. You do not need to participate in this study to have your [insert condition] treated.

**Consent:** I understand that my participation in this study is entirely voluntary and that I may refuse to participate or withdraw from the study at any time without penalty. I understand the procedures described above, and I understand fully the rights of a potential subject in a research study involving people as subjects. My questions have been answered to my satisfaction. I agree to participate in this study. I have received a copy of this consent form.

􀀀 I agree to be audio taped 􀀀 I do not agree to be audio taped

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Participant Name Printed Participant Name Signed Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_

Parent of participant (if under 18) Parent Name Signed Date

Name Printed

I have explained the research to the subject or his/her legal representative, and answered all of

his/her questions. I believe he/she understands the information described in this document and freely consents to participate.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Principal Investigator Date:

**PI Name**

**Address**

**Phone**

**Email**