Consent Form Template Instructions

- The consent form should be written at no greater than an eighth grade reading level and using lay person language (i.e., no complex scientific or medical terms).

- In the following template:
  - The consent form should be written in the second person, e.g., "You will be asked to…."
  - If the consent form is for the involvement of children in a study, "you" should be replaced with "your child."

- If printed, pages of the consent form should be numbered.

- If the IRB requires the researcher to obtain signed consent forms from participants, the researcher must keep the signed consent form as part of the research files for a minimum of three years after the end of the study, and provide a copy to each participant.

- If you are seeking "broad consent" please visit the Loyola IRB webpage for more information.

Please make a copy of the following template to your own drive. This form and all recruitment materials must be included with your protocol materials.

CONSENT FORM FOR PARTICIPATION IN A RESEARCH STUDY

RESEARCHER(S) AND TITLE OF STUDY

Identify yourself and give your contact information. If this is a student project, the faculty supervisor serves as the principal investigator and their contact information should also be included. For example:

I am/we are asking you to participate in a research study titled *"TITLE". I/We* will describe this study to you and answer any of your questions. This study is being led by *Name of PI, Department at Loyola University. (If the researcher is a student)* The Faculty Advisor for this study is *Name, Department at Loyola University. (If externally funded)* This study is being funded by a *grant/contract/gift* from *Name of Sponsor/Funder.*

WHAT IS THE PURPOSE OF THIS FORM?

This consent form describes the research study and helps you to decide if you want to participate. It provides important information about what you will be asked to do in the study, about the risks and benefits of participating in the study, and about your rights as a research participant. You should:

- Read the information in this document carefully.
- Ask the researcher any questions, particularly if you do not understand something.
- Not agree to participate until all your questions have been answered, or until you are sure that you want to.

WHAT IS THE PURPOSE OF THIS STUDY?

State the purpose of the research in as few words as necessary and in a manner that participants will be able to understand, e.g., "The purpose of this research is....."

State the anticipated number of participants who will be involved in the study.

Where appropriate, state that participants must be at least 18 years old to participate in the study.

If your study involves deception, you may not need to list the entire purpose of the study, but a debriefing form will be required.

WHAT DOES YOUR PARTICIPATION IN THIS STUDY INVOLVE?

I/We will ask you to…

- Explain in simple, non-scientific language what will happen to the participant or what they will be asked to do in the study. Describe the participant time commitment for each component, as well as the total time for participation. All procedures listed in the IRB application and funding proposal should be described, and any experimental procedures (interventions, manipulations, treatments) specifically noted.

WHAT ARE THE POSSIBLE RISKS OF PARTICIPATING IN THIS STUDY?

In simple, non-scientific language, describe any reasonably foreseeable risks or discomforts:

- Legal risks (e.g., possibility of discovering activities that may require reporting to authorities, possibility of being arrested)
- Physical risks (e.g., nausea, muscle aches, rashes, infection, discomfort)
- Social or economic risks (e.g., loss of confidentiality; effect on financial standing, employability, or insurability)
- Emotional risks (e.g., feelings of sadness or anxiety)

If you study presents minimal risk, please state this (e.g., "Participation in this study is expected to present minimal risk to you.") Note: All research involves some degree of risk, even if it is a simple time commitment.

If your study may cause significant distress, please direct your participants to the following resources based upon their community status:

Students *at Loyola:*
Counseling and Career Services Office, 208 Danna Center, 504-865-3835

Faculty/Staff *at Loyola (if applicable):*
Contact Aetna's EAP program. More information is available on Loyola's human resource webpage:
https://finance.loyno.edu/human-resources/human-resources-manual-employee-assistance-program-eap.

Other Populations: (if applicable) *please provide relevant resources.*

WHAT HAPPENS IF YOU GET SICK OR HURT FROM TAKING PART IN THIS STUDY?

Include this section (including title) only if applicable.

If you are injured or require medical treatment, you may seek treatment from your primary care provider or, if eligible, from University Health Services. Loyola University is not responsible for the cost of any care required as a result of your participation in this study.

WHAT ARE THE POSSIBLE BENEFITS OF PARTICIPATING IN THIS STUDY?

Describe the potential benefits that participants may reasonably expect from participating in the research. If there are no direct benefits to participants, state this and explain the benefits of the knowledge to be gained through the study.

Note: Compensation, financial incentives, learning about how experiments are conducted, receiving a gift, or earning extra credit for being a research participant are not "benefits" and should not be listed here. These go under the next "compensation" section.

WILL YOU RECEIVE ANY COMPENSATION FOR PARTICIPATING IN THIS STUDY?

Indicate whether the participant will receive incentives/compensation or extra credit for being in the study. If participants will not receive any incentives, state this. If students will receive course credit for participation, ways of earning equivalent credit without participating in the research should be described here.

If identifiable information will be shared with Loyola finance, Procurement, etc., to process payments, include the following: Your name and contact information may need to be shared with Loyola University finance staff to process your payment, but they will not receive any research data or other details about the study.

AUDIO/VIDEO RECORDING: (if applicable - remove if not part of study)

If audio and/or video recording devices will be used, explain why these are needed and what will be done with them upon completion of the research (kept indefinitely, archived after transcription, destroyed after X years).

ONLY IF USING A SIGNED CONSENT, provide a separate signature line for the participant to be audio/video recorded, if the recording is optional for participation. For example:
Please sign below if you are willing to have this [interview/focus group/activity] recorded (specify audio or video). You may still participate in this study if you are not willing to be recorded.

☐ I do not want to be recorded.
☐ I am willing to be recorded:

Signed: _____
Date: _____

If you will take photographs or make audio, video, or other recordings that you want to use for activities beyond research analysis (publications, presentations, other promotional purposes), include a section that:

- Informs the participant that you are making a [type(s) of media used] recording in which the person's name, likeness, image, and/or voice will be included;
- Asks the participant to grant you the right to make, use and publish recordings in whole or in part in media forms now known (such as film, slides, and digital audio) or developed in the future. This includes the right to edit or duplicate any images/recordings;
- Explains the limitations on reproduction, distribution, performance, or display of images/recordings;
- Explains that the participant does not have rights to inspect or approve the finished product or printed/published matter that uses the images/recordings or versions of the images/recordings; and
- Explains that the participant will not receive any financial compensation for commercial and/or non-commercial (as appropriate) uses of the images/recordings.

The same signature line above may be used for this performance release information.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

Taking part in this study is completely voluntary. You may choose not to take part at all. If you agree to participate, you may refuse to answer any question. If you decide not to participate, you will not be penalized or lose any benefits for which you would otherwise qualify.

If completing all research materials (e.g., answering all survey or interview questions; meeting a minimal requirement of entries in a weekly/monthly log) is required for participation, you must make this condition clear to them here. State that people can choose not to participate if they are uncomfortable with these conditions.

CAN YOU WITHDRAW FROM THIS STUDY?

If you agree to participate in this study and you then change your mind, you may stop participating at any time. Any data collected as part of your participation will remain part of the study records *(modify this sentence where applicable)*. If you decide to stop participating at any time, you will not be penalized or lose any benefits for which you would otherwise qualify.

HOW WILL THE CONFIDENTIALITY OF YOUR RECORDS BE PROTECTED?

Explain briefly, and in lay terms, how you will protect the participant's privacy and/or confidentiality.

- De-identification of data
- If you will completely de-identify data, or keep identifying information separate from research data (e.g. signed consent forms kept separate from the survey data and the two will not be connected)
- If you plan to keep identifying information with the data, state this here
- If you are not planning to collect any identifying information at all (as in anonymous surveys).
- Physical security of data/research files
- Who will have access to identifying information
- How will sensitive data be kept secure in an electronic environment

This next section is required for all federally funded research, and recommended for all other studies:

We will do our best to keep your participation in this research study confidential to the extent permitted by law; however, it is possible that other people may need to review the research records and may find out about your participation in this study. For example, the following people/groups may check and copy records about this research:

- The Office for Human Research Protections in the U. S. Department of Health and Human Services
- (For sponsored studies, add:) The research study sponsor, *Name of Sponsor*

· Loyola University's Institutional Review Board (a committee that reviews and approves research studies)

If using Qualtrics for survey collection, include the following statement:
We anticipate that your participation in this survey presents no greater risk than everyday use of the Internet.

If using another survey vendor to administer online surveys, include the following statement:
Please note that the survey(s) [is/are] being conducted with the help of [company name], a company not affiliated with Loyola and with its own privacy and security policies that you can find at its website. We anticipate that your participation in this survey presents no greater risk than everyday use of the Internet.

If your study involves focus groups, include the following sentence.
While I plan to maintain confidentiality of your responses, other focus group participants may repeat responses outside the focus group setting.

When the research involves e-mail communication, include the following statement:
Please note that email communication is neither private nor secure. Though [I am/we are] taking precautions to protect your privacy, you should be aware that information sent through e-mail could be read by a third party.

For sensitive research data with identifiers, stored in the cloud or on servers, or transmitted via the internet, consider including the following statement:
Data may exist on backups and server logs beyond the timeframe of this research project.
OR
Your confidentiality will be kept to the degree permitted by the technology being used. We cannot guarantee against interception of data sent via the internet by third parties.

If your study may lead to disclosure of information covered by Louisiana mandatory reporting laws, such as suspected child abuse and/or neglect, or Federal laws relating to sexual harassment and violence include the following sentence and applicable bulleted language.

I am also required by law to report certain information:

- To government and/or law enforcement officials (e.g., child abuse, threatened violence against self or others, communicable diseases), or
- To appropriate Loyola University authorities (e.g., disclosures involving Sexual Violence - which includes sexual harassment, sexual assault, unwanted sexual contact, sexual misconduct, domestic violence, relationship abuse, stalking [including cyber-stalking] and dating violence).

Sharing De-identified data collected in this research

(**If you may share data without identifiers:** We strongly recommend that you include this section in your consent, to inform participants that you may share de-identified data you collect from them. Certain sponsors now require researchers to make available their de-identified data to the research community, as do a growing number of journals. If you choose not to include the following language and later wish to share de-identified data, you may not be able to do so without re-contacting participants to obtain consent.)

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Whom to contact if you have questions about this study

If you have any questions pertaining to the research you may contact (*insert PI's name and contact information)* to discuss them.

If you have any questions or concerns regarding your rights as a subject in this study, you may contact the Institutional Review Board (IRB) for Human Participants at Dr. Erin Foster: 504-865-3134, erin.foster@loyno.edu or Dr. Michele Ellis: mellis@loyno.edu.

Statement of consent

Include the next segment only if you are using signed, written consent. **Signed consent may not be necessary for certain minimal risk social and behavioral research**, and you can instead request a waiver of documentation of consent. Furthermore, signed consent cannot be used if you tell participants that your study is anonymous. For online studies, see below.

I have read the above information, and have received answers to any questions I asked. I consent to take part in the study.

Your Signature_____Date

Your Name (printed)

Signature of person obtaining consent_____Date

Printed name of person obtaining consent

[For signed forms] This consent form will be kept by the researcher for at least three (3) years beyond the end of the study.

If the consent information is for participation only in a web-based survey, (e.g., using Qualtrics), replace the participant signature block above with the following format for participants to give consent or decline participation.

- o Click here if you confirm you are at least 18 years of age and consent to participate in the research study.
- o Click here if you decline to participate in the research study.