**Information for Investigators**

Use this type of CONSENT FORM for research projects that involve:

* Research participants who are ADULTS (age 18 and over).
* Always have two copies of the informed consent for each potential participant. One signed copy is kept by the PI or research team, and the other is to be given to the enrolled participant after written consent is given.

Please remove the *red notes* before finalizing your consent form.

 

**Consent to Participate in a Research Study**

 *(Insert PI name)*, Principal Investigator

*Project Title: (insert title here)*

We are asking you to choose whether or not to volunteer for a research study. These pages give you information to help you decide whether to participate. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

**WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?**

* ***Briefly*** *describe the purpose of the study and the procedures to be followed in lay terms.*
* *Explain technical terms so that information is clear to participants.*

By doing this study, we hope to learn \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Your participation in this research will last about {*state in hours, days, months, years*}.

**WHAT WILL YOU BE ASKED TO DO?**

*Tell the participant what to expect.*

* *Give a timeline description of the procedures that will be performed.*
* *Answer the following for the participant:*
	+ *What is being performed as part of the research?*
	+ *For studies that also include involvement of routine program or training participation, differentiate procedures being conducted solely for research.*
	+ *Clearly identify any procedures that are experimental.*

**WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?**

*If there are risks to participation, describe them for each procedure.*

* *When applicable, group the risks into those that are expected, ranking them as rare, occasional, or often, and describe them as such.*
* *When applicable, in lay terms, list* ***all reasonably*** *expected side effects and those that are life-altering or potentially life-altering, no matter how rare.*
* *Explain risks with ramifications, if applicable. For example, what could happen if the participant experiences tightness in his/her chest during physical exercise being done for the study, or what are the consequences of a breach of confidentiality relative to sensitivity of personal information?*
* *Include significant risk of social, psychological, emotional, or financial harm (e.g., breach in confidentiality in sensitive research).*

*The risk section must also contain the following statement, when applicable:*In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

**WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?**

We do not know if you will get any benefit from taking part in this study. However, some people have experienced \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *{insert potential benefit; please note that payment to subjects is not considered a benefit;* *payment details should be described in the “reward” section below}* when \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *{qualify when potential benefit experienced}.* However, if you take part in this study, information learned may help others.

***OR***

You will not get any personal benefit from taking part in this study.

**DO YOU HAVE TO TAKE PART IN THE STUDY?**

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer. You can stop participating in this study at any time without penalty or loss of benefits you would normally have.

*Add the following for student volunteers:* As a student, if you decide not to take part in this study, your choice will have no effect on your academic status or class grade(s).

**IF YOU DON’T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?**

*Include as necessary; otherwise delete this section.*

If you do not want to take part in the study, there are other choices such as \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(describe whether or not there are any activities the participant could do in order to receive the same level of benefit).*

**WHAT WILL IT COST YOU TO PARTICIPATE?**

There are no costs associated with taking part in this study.

***OR***

*Describe any costs the subject may incur as a result of participating in the study (e.g., transportation, parking, data charges for mobile devices). For example:* You may have to pay for the cost of getting to the study site and a parking fee.

**WHO WILL SEE THE INFORMATION THAT YOU GIVE?**

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. *{Insert description of procedure(s) used for protecting confidentiality of data, including paper records, computer records, jump drives, and portable storage devices.}*

You should know that there are some circumstances in which we may have to show your information to other people because they have the legal right to review research records. For example, the law may require us to share your information with authorities, if you have a reportable disease; if you report information about a child being abused; and/or if you pose a danger to yourself or someone else. The Franklin University Institutional Review Board has the right to review research records for this study.

*Add the following information if online data collection applies to study:* We will make every effort to safeguard your data, but as with anything online, we cannot guarantee the security of data obtained via the Internet. Third-party applications used in this study may have Terms of Service and Privacy policies outside of the control of Franklin University.

**CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?**

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. *Include the following information, if applicable:* This may occur for a number of reasons. You may be removed from the study if:

* you are not able to follow the directions,
* we find that your participation in the study is more risk than benefit to you, or
* the agency paying for the study chooses to stop the study early for a number of scientific reasons.

**WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?**

You will receive \_\_\_\_\_\_\_\_ for taking part in this study*. {If this is a monetary reward/payment, explain how this will be prorated should the participant choose to withdraw early. If this is not a cash payment, the IRB strongly suggests that the reward be given to the participant regardless of completion of the study.}*

***OR***

You will not receive any rewards or payment for taking part in the study.

**WILL THERE BE ANY AUDIO OR VIDEO RECORDING?**

*If no audio or video recording is used during the study, this section may be deleted.*

This research study involves audio and/or video recording. This recording will be available to the researcher, the Institutional Review Board and other representatives of this institution, and any of the people who gave the researcher money to do the study *{if applicable}*. *Explain why recording is necessary, what you will do with the recordings, and what measures you will take to protect the privacy of the individuals who agree to be recorded.*

**WILL YOUR INFORMATION BE USED FOR FUTURE RESEARCH?**

*One of the following statements is required if* ***any*** *identifiable samples or* ***any*** *identifiable private information is collected:*

Your information collected for this study will NOT be used or shared for future research studies, even if we remove the identifiable information like your name, clinical record number, or date of birth.

***OR***

All identifiable information (e.g., your name, clinical record number, or date of birth) will be removed from the information or samples collected in this study. After we remove all identifiers, the information or samples may be used for future research or shared with other researchers without your additional informed consent.

**WHAT ELSE DO YOU NEED TO KNOW?**

*Insert these additional pieces of information where they best fit in this document.*

*This statement may not be applicable:* If you volunteer to take part in this study, you will be one of about \_\_\_\_\_\_\_ people to do so.

*If the lead investigator (NOT PI) is a student,**he/she should disclose this fact and add the following sentence:* I am being guided in this research by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *{Dissertation Committee Chair}.* There may be other people on the research team assisting at different times during the study.

*Disclose what institution(s) (such as NIH, NSF, etc.) or companies are involved in the study through funding, cooperative research, or by providing study drugs or equipment. An example of such a statement would be as follows:*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *{name of institution/company}* is providing financial support and/or material for this study.

**WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?**

The person in charge of this study is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *{Principal Investigator, PI}* of Franklin University, Department of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ {*list department}.* If you have questions, suggestions, or concerns regarding this study, or if you want to withdraw from the study, his/her contact information is: {*PI contact information}*.

If you have any questions, suggestions, or concerns about your rights as a volunteer in this research, contact the Franklin University IRB Office at 614-947-6037 or irb@franklin.edu.

**INFORMED CONSENT SIGNATURES**

You are not required to participate in this study. In the event you do participate, you may leave this research study at any time. If you leave this research study before it is completed, there will be no penalty to you, and you will not lose any benefits to which you are entitled.

If you agree to participate in this research study, sign this section. You will be given a signed copy of this form to keep. You do not waive any of your legal rights by signing this form.

*(As applicable) Please indicate your decision about being (audio or video recorded) by initialing next to “Yes” or “No”:*

*\_\_\_\_\_ Yes \_\_\_\_\_ No I consent to be audio recorded for the {insert interview/focus group/etc.} portion of this research.*

*\_\_\_\_\_ Yes \_\_\_\_\_ No I consent to being video recorded for the {insert interview/focus group/etc.} portion of this research.*

**SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE:**

* You have read and understand the above information.
* Your questions about the research have been answered to your satisfaction.

**Name of Participant (Print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Participant’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of the Person Obtaining Consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**