**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 and other text that does not apply to your study before finalizing your consent form.



**Consent to Participate in a Research Study**

{Insert PI name}, Principal Investigator

Project Title: {Insert title here; this should match the title of your protocol}

*Project Title: (insert title here)*

You are invited to take part in a research study conducted by {Name of PI/Student Investigator and Co-PI/Dissertation Committee Chair, if applicable} from the {department or program} at Franklin University in Columbus, Ohio. Before you decide whether or not to participate in the study, you should read this form and ask questions if there is anything that you do not understand.

***PURPOSE****:* The purpose of the study is {describe the nature and purpose of the research in layperson’s language}.

***WHAT YOU WILL DO IN THE STUDY****:* If you decide to take part in this study, here is what will happen: {Explanation of what will happen to the subject; what type of information will be sought; state what portions, if any, are considered experimental.}

***TIME REQUIRED*:** Participation will take approximately {enter time}.

***RISKS OR DISCOMFORTS:***{Explain any risks or discomfort - including psychological discomfort - that might reasonably be expected to happen. If identifiable information is collected, then state:} There is a risk that your identifiable information could be accidentally disclosed; however, the researchers are taking measures to protect your data.

***BENEFITS OF THIS STUDY****:* {Describe benefits to the subject, or to others, of this study. If there is no direct benefit to the subject, include a sentence to the following effect:} Although there will be no direct benefit to you for taking part in this study, the researcher may learn more about {description}.

***DECISION TO TAKE PART IN THE STUDY****:* {Use words to the following effect:} 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. {If study involves survey or interview questions:} You may skip any questions you do not wish to answer. {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).

***RIGHTS AND CONCERNS****:* If you have questions about this research, please contact {investigator’s name, research title, phone number, and email address}. You may also contact the faculty member supervising this work: {name, title, address, phone number, and email address}. If you have any questions regarding your rights as a research participant, please contact the Franklin University IRB Office at 614-947-6037 or irb@franklin.edu.

***CONFIDENTIALITY****:* {Describe how you will maintain the confidentiality of records that identify the subject. Use words to the following effect, if appropriate:} The information that you give in the study will be handled confidentially. Your name will not be used in any report. Identifiable research data will be encrypted and password protected.

{If you will be coding the data, use words to the following effect:} Your responses will be assigned a code number. The list connecting your name to this code will be kept in an encrypted and password protected file. Only the researcher will have access to the file. When the study is completed and the data have been analyzed, the list will be destroyed.

{If data will be collected over the Internet, use words to the following effect:} While researchers follow procedures to maintain your confidentiality, as with any internet activity, we cannot guarantee confidentiality of interception of data sent via the Internet by any third parties.

{If you are using an audio or video recording, or photographs in the study, describe if and when such materials will be destroyed. Use words to the following effect:} With your permission, I would like to audiotape this interview so that I can make an accurate transcript. Once I have made the transcript, I will erase the recordings. Your name will not be in the transcript or my notes.

{For a focus group, use words to the following effect:} You will not be identified in any report or publication of this study. Even though we will tell all participants in the study that the comments made during the focus group should be kept confidential, it is possible that participants may repeat comments outside the group.

{If the study will be anonymous, use words to the following effect:} The information that you give in the study will be anonymous. Your name will not be collected or linked to your answers. {If it is possible to deduce the participant’s identity through their responses, state the following:} Because of the nature of the data, it may be possible to deduce your identity; however, there will be no attempt to do so and your data will be reported in a way that will not identify you.

{If the study involves information that legally must be reported to government agencies, then include the following:} Your part in this study is confidential within legal limits. The researchers will protect your privacy unless they are required by law to report information to city, state, or federal authorities, or to give information to a court of law. Otherwise, none of the information will identify you by name. All records will be {describe how they are to be maintained}.

***FUTURE RESEARCH:*** {Use one of the following statements if collecting identifiable data/specimens:}De-identified information or biospecimens might be used for future research without additional consent. {OR} Your information or biospecimens will not be used or distributed for future research studies.

{Use this statement if identifiable data/specimens might be used in future research:}

With your permission, researchers may use your identifiable information for future research {describe how the data may be used and how confidentiality will be protected}.

***ALTERNATIVES:*** *(If applicable)*{List any alternatives available to the subject for obtaining the same benefit without participating in research – e.g., alternative therapies, in the case of clinical trials, or alternative assignments worth the same academic credit for comparable effort:}

***COMPENSATION:*** *(If applicable)* You will receive {$X or/ X credits} for participating in this study.

***IN CASE THERE IS ANY INJURY TO THE SUBJECT****: (If applicable, for greater than minimal risk studies)* {Explain whether any medical or other treatment is available if injury occurs, and who to contact; use words to this effect:} If this study causes you any injury, you should write or call {names} at {phone number}.

***NIH CERTIFICATE OF CONFIDENTIALITY:*** *(*[*If applicable*](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html)***)*** To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

{Use the following language as applicable:} The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

{Language such as the following should be included if researchers intend to make voluntary disclosure about information obtained in the research such as child abuse, or intent to hurt self or others:} The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of {list what will be reported, such as child abuse and neglect, or harm to self or others}.

***SIGNATURE****:*

Signing this document means that information in this form was provided to you and that you voluntarily agree to participate in the research described above.

{A checklist can be used if appropriate; modify as needed}:

\_\_\_ I agree to be interviewed.

\_\_\_ I agree to have my interview audiotaped.

\_\_\_ I give my permission for my {specify identifiable or de-identified} data to be retained and used in future studies described above.

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Signature of Participant Date

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

Typed/Printed Name

***Please sign both consent forms, keeping one for yourself.***