**IRB WRITTEN CONSENT FORM MODEL and INSTRUCTIONS**

**Please do not include a copy of this exact model in your proposal and do not include the italicized information explaining what should be in each section. Your proposal must include a consent form that has been tailored specifically to your study. You can use this basic wording, but format it to present the information clearly (see the sample at the of this document for formatting) and modify the content to be correct for your study.**

**Remember the goal of the informed consent process is to inform participants of what they will be doing in the study, what the risks and benefits are to them, and to address confidentiality and participant rights. A list of required elements and more information can be found in the SMCM** [**eIRB Forms Instruction**](https://www.smcm.edu/irb/forms/) **document.**

**Template/Instructions:**

*Start with an invitation and the title of study. This title does not need to reveal the specific topic of your study if that would be counter to research goals.*

You are invited to participate in the study entitled “Anxiety at St. Mary’s College.”

*This first paragraph should provide an overview of your project including a brief description of the tasks that the participant will be asked to complete.*

We are performing research on how anxiety affects students’ lives. You will be asked to fill out three short surveys related to anxiety. Your total participation time will be approximately 30 minutes.

*The next section should address any risks. NOTE: Online studies can skip the COVID risk statement and proceed to the general risks section. However, ALL IN-PERSON RESEARCH for the 2021-2022 academic year should include* ***IN BOLD*** *the following COVID statement on the consent form:*

**To participate in this study, you must appear in person. The evidence to date suggests that COVID-19 and its variants are most easily spread through person-to-person contact. Although the researchers have safeguards in place to reduce the likelihood of transmission, it may still be possible to become infected. In signing this consent form, you acknowledge that you understand this risk and wish to participate.**

*After the COVID warning, address more general risks. Use the wording that best fits your project (select one to include—not all of them—or modify as needed):*

* *If there are no risks:* We do not foresee any risks to participating in the research tasks. If you are asked questions or given tasks that make you uncomfortable, you may refuse to answer any question that you do not wish to answer or withdraw from the study.
* *If there are other risks:* You should state what those risks are so that the participant can make an informed decision.

*The next section should describe the benefits. Use the wording that best fits your project (select one to include—not all of them—or modify as needed):*

* *No benefits:* There is no direct benefit to you from participating in this research, but your data will help us understand how anxiety influences students’ lives.
* *If you are using some other type of incentive:* As an incentive to participate, you will receive X. Your data will help us understand how anxiety influences students’ lives.
* *If you are psychology student using the psychology department research pools OR the psychology department raffle incentive, please see the more specific guidelines on the* [*psychology department webpage*](https://www.smcm.edu/psychology/student-resources/obtaining-research-participants/student-resources-obtaining-research-participants-irb-language/)*.*

*The next section should describe the confidentiality aspects of your study. Use the wording that best fits your project (select one to include—not all of them—or modify as needed):*

* *If no identifying information is being collected (it is anonymous):* Because there is no identifying information on the surveys and this consent form will be in no way linked to your surveys, your answers to the survey questions will be anonymous.
* *If data is not anonymous but will be confidential (collected by the researcher but not shared):* We will be collecting some information that may mean you could be identified from your responses. To protect your confidentiality, researchers will keep all data stored on a password protected computer and only the researchers will have access to the data. We will remove any identifiers from the data at the conclusion of data collection.
* *In cases where the researchers will not have access to identifiers, but the Office of Institutional Research or a staff member must have access to identifiers for follow up with non-responders (if using Qualtrics and an all student email approach) or to award credit or raffle entries (e.g., in* [*Psychology studies*](https://www.smcm.edu/psychology/student-resources/obtaining-research-participants/student-resources-obtaining-research-participants-irb-language/)*):* We will be collecting some information that may mean you could be identified from your responses. To protect your confidentiality, only members of the Institutional Research Staff [*and for psychology studies, the Research Pool Manager*] will have access to identifying information (email addresses) but will keep this information confidential. Researchers will not have access to identifying information and will keep the anonymous data stored on a password protected computer.
* *If recordings are made:* You may be audiotaped/videotaped as part of this study. To protect your confidentiality, researchers will keep all recordings on a password protected computer and only the researchers will have access to the recordings. Identifying information will be removed from any transcriptions of the recordings. At the conclusion of the research, all recordings will be destroyed.
* *If you are not guaranteeing confidentiality, you MUST state clearly how their information will be used. This example is just one example—make sure you say how you plan to use non-confidential data:* Information in this study is not confidential and you may be able to be identified by others. Your answers [recordings] may be used publicly where you could be identified. If you are not comfortable with this, you may choose not to participate at any time and your responses will not be used.

If you are interested in discussing the research further please contact [*use your contact information*] S. Freud at 240-555-5555 or sfreud@smcm.edu or 5555 Oedipus Complex, St. Mary’s City, MD 20686. If you have any questions regarding your rights as a participant in this study please contact the Chair of the Institutional Review Board at St. Mary’s College of Maryland, at irb@smcm.edu, or 18952 E. Fisher Rd., St. Mary’s City, MD 20686.

Your participation in this research is voluntary and you may choose not to participate at any time. Your decision whether or not to participate will not jeopardize your future relations with St. Mary's College of Maryland.

You must be 18 years of age or older to participate in this research.

Signed \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signed \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

####  Investigator Study Participant

### Date of Birth \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

##### Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**CONSENT FORMS MUST BE RETAINED BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE PROVIDED TO THE PARTICIPANT!**

See: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.117>

**Here is a final consent form SAMPLE using the points above but without the explanatory language and with consistent formatting:**

You are invited to participate in the study entitled “Anxiety at St. Mary’s College.”

We are performing research on how anxiety affects students’ lives. You will be asked to fill out three short surveys related to anxiety and your total participation time will be approximately 30 minutes.

**To participate in this study, you must appear in person. The evidence to date suggests that COVID-19 and its variants are most easily spread through person-to-person contact. Although the researchers have safeguards in place to reduce the likelihood of transmission, it may still be possible to become infected. In signing this consent form, you acknowledge that you understand this risk and wish to participate.**

We do not foresee any risks to participating in the research tasks. If you are asked questions or given tasks that make you uncomfortable, you may refuse to answer any question that you do not wish to answer or withdraw from the study.

There is no direct benefit to you from participating in this research, but your data will help us understand how anxiety influences students’ lives.

Because there is no identifying information on the surveys and this consent form will be in no way linked to your surveys, your answers to the survey questions will be anonymous.

If you are interested in discussing the research further please S. Freud at 240-555-5555 or sfreud@smcm.edu or 5555 Oedipus Complex, St. Mary’s City, MD 20686. If you have any questions regarding your rights as a participant in this study please contact the Chair of the Institutional Review Board at St. Mary’s College of Maryland, at irb@smcm.edu, or 18952 E. Fisher Rd., St. Mary’s City, MD 20686.

Your participation in this research is voluntary and you may choose not to participate at any time. Your decision whether or not to participate will not jeopardize your future relations with St. Mary's College of Maryland.

You must be 18 years of age or older to consent to participate in this research.

Signed \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signed \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

####  Investigator Study Participant

### Date of Birth \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

##### Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_