 **Institutional Review Board (IRB)**

**Instructions for (ICF) Parental/Guardian Consent Template**

**You should use this consent form template only if:**

1. You are conducting research with minors (under 18 years of age) **and**
2. Your research poses no greater than minimal risk to minor participants **and**
3. You are seeking parental/guardian consent for research on minors/children.

**You should not use this consent form template if:**

1. You are doing research with adult participants **and/or**
2. Your research poses greater than minimal risk to minor participants.

Risk level is assessed in view of potential harms to participants – these include social, legal, emotional, psychological etc. harms, not just physical harms. Depending on the subject matter with which the research deals and the specific way in which the research is carried out, a study may be considered greater than minimal risk even when using survey or interview (including focus group) methodologies.

**Note:** According to DHHS Regulations “minimal risk” means: “The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

This template is intended to serve as a **GUIDE**. You may need to provide more information and details than are stated in the template. You will most likely need to re-word sentences and/or add your own sentences. You may also need to add information or details that are not directly asked for in the template. Again, this template is intended to serve as a **GUIDE** and is not exhaustive.

**Remember: the Consent Form should contain only information that is applicable and relevant to your study.**

**IMPORTANT:** You should remove the red guidance text as you go through this document, by filling out information specific to your study and/or deleting irrelevant and unnecessary text. The red sentences indicate sections that must be completed by the author of the Consent Form, or serve as guidance and suggestions about what should be included. There should be **no** red sentences left anywhere in the completed Consent Form.

**PLEASE PROOF READ** your completed Consent Form before submitting it. Seemingly minor spelling, grammar, and formatting errors may require you to revise and re-submit, causing unnecessary delays.

**PLEASE DO NOT INCLUDE** these instructions in your completed Consent Form.

**NOTE: SEE CHILD ASSENT FORM for CHILDREN under the age of 12.**

 **Department of (**Name)

**Parental/Guardian Consent Form**

**FOR CHILD’S PARTICIPATION IN A RESEARCH PROJECT**

**Project Title:** (Title)

**Principal investigator:** (PI’s name)

**Mentor:** (Mentor’s name) *Include only* *if PI is a student.*

**SPU Sponsor:** (Sponsor’s name) *Include only* *if PI is not affiliated with SPU.*

**Introduction**

You are invited to consider allowing your child to participate in this research study. Please take as much time as you need to make your decision. Feel free to discuss your decision with whomever you want, but remember that ***the decision to allow your child to participate, or not to participate, is yours***. If you decide that you allow your child to participate, please sign and date where indicated at the end of this form.

**Purpose**

The purpose of this research is to (the reason(s) the research is being conducted, including what the results will be used for).

**Procedures**

Your child is being asked to take part in this study because she/he is (part of study’s target population – *state what criteria the participant meets*). About (number) subjects will take part in this study at (location(s) of study).

If you decide to allow your child to participate in this study, she/he will (*describe fully* what participant will be expected to do or take part in. *Explain the procedures and schedule, focusing on what the subject will be expected to do, e.g. complete surveys, questionnaires, interview, etc.*).

The research will be looking at (the research topic/subject as well as the general types of questions. *Do not list specific questions. However, be sure to mention whether the research deals with issues that might be considered sensitive or controversial, e.g. sexual behavior, drug or alcohol use, other illegal activities etc.*).

Your child will be in the study for about (anticipated duration of the session or sessions).

*If applicable:* Your child will also be contacted for follow-up (at what point? *– state when in the future participants will be contacted*) (how? *– explain through what means participants will be contacted*).

If the study involves videotaping or audio recording, mention this here.

If there are additional components to the study plan, please be sure to include them in this section.

You or your child can stop participation at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher first.

**Risks**

There are (amount*, e.g. no, minimal, very few, few, a number of*) risks associated with participating in this research.

*If there are any risks whatsoever, include the following:*

It is possible, but (probability*, e.g. unlikely*), that this research could cause (harm*, e.g. embarrassment, distress, employer problems*) if (circumstance that could cause risk*, e.g. others learn of your responses, you have a strong emotional reaction to* [topic]*, your employer finds out and is unhappy*).

Make sure to consider all types of risks, including physical, psychological, emotional, social, economic, and legal risks. *(Possible examples: embarrassment if private information about you is accidentally disclosed to others, emotional distress from having to answer personal questions, criminal or civil liability, etc.)*

*(For each risk, include:* The researcher will try to reduce this risk by (state steps taken to mitigate specific risk).)

**Benefits**

If you agree to let your child take part in this research study, there will be no direct benefits to him/her *(or describe any direct benefits to the participant)*. However, information gathered in this research may (reasonable result*, e.g. provide insight into* [topic] *or help us understand* [topic]).

*(If applicable: State any alternative procedures or treatments that are available or may be of greater benefit to the participant).*

**Confidentiality**

*Please revise this entire section to make it applicable to your project.*

Every effort will be made to keep any information collected about your child confidential, in accordance with the law. However, it is impossible to guarantee absolute confidentiality.

In order to keep information about you safe, (steps that will be taken to protect data*, e.g. data will be kept in a password-protected file on the researcher’s personal computer which only the researcher can access, study data will be kept in a locked box at the researcher’s office etc.*).

Include additional information, as listed below, on how different types of data will be kept secure.

This section should include a description of:

a) What data will be kept and in what form *(e.g. digital, paper – each type of data should have its own distinct safety plan),*

b) Whether the data will be identifiable *(e.g. linked through a code, directly linked to participant names etc.),*

c) Where and how data will be securely stored *(e.g. password-protected computer, locked filing cabinet etc.),*

d) Who will have access to the data,

e) Whether identifiable data will be shared outside the researcher team *(if so, with whom, how and why)*,

f) Whether *(and if so, how and when)* identifiers will be destroyed.

*Revise or delete as applicable to this project:*

We would like to include your child’s name in the (final goal*, e.g. thesis, publication, essay, presentation*) that result(s) from this research project. We want to (level of identification*, e.g. identify, describe*) your child for attribution and explanatory purposes. However, you have the option not to have your child’s name used when data from this research are published; if this is the case, please (procedure*, e.g. indicate so on the last page of this form, etc.*). Please note that, even if your child’s name is not used in publication, the researcher *(if applicable:* and the research team*)* will still be able to connect your child to the information gathered about him/her in this research.

*If there are any psychological or physical risks to participants, include this section.* ***If there are no such risks, do not include this section:***

**Policies and Procedures for research-related injuries**

Researchers will make every effort to prevent research-related injuries and illnesses. If you are injured or become ill while you are in the study, you will receive emergency medical care. The costs of this care will be charged to you or to your health insurer. No funds have been made available by Saint Peter’s University or its affiliates, or any government agency, to compensate you for a research-related injury or illness.

**Your Rights As A Research Participant**

Participation in this study is entirely voluntary at all times. Your child can choose not to participate at all or to leave the study at any point. If you, or your child, choose not to participate or to leave the study, there will be no effect on you or your child’s relationship with the researcher(s) or any other negative consequences *(if applicable:* and you and your child will get the same (benefits/care) as you would without the study*)*.

If you, or your child, decide that you no longer want to take part in this research, you are encouraged to inform the researcher of your decision. *Please include/revise the following as applicable to your project:* The information already obtained through your participation (will/will not) be included in the data analysis and final report for this research.

**Questions or concerns**

If you have questions about this research project, you may contact (PI’s Name) at (phone number) or (email address). *(If applicable:* You may also contact the researcher’s faculty mentor, (Mentor’s Name) at (phone number) or (email address). If you have any questions about your rights as a research participant, please contact the Saint Peter’s University IRB at (201) 761-6306 or [jfeinberg@saintpeters.edu](http://jfeinberg@saintpeters.edu)

*If applicable to this study:*

**Statement of Person Obtaining Informed Consent**

I have fully explained this research to the participant. I have discussed the purpose and procedures, the possible risks and benefits, and that participation in this research is completely voluntary. I have invited the participant to ask questions and I have given complete answers to all of the participant’s questions.

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Signature of Person Obtaining Informed Consent Date

**Consent of parent or guardian on behalf of child participant**

I understand all of the information in this Consent Form. I have gotten complete answers for all of my questions. I freely and voluntarily agree to allow my child to participate in this study.

*If subjects may be photographed/videotaped/audio recorded/etc. as part of the study include (otherwise, delete):*I understand that my child will be (photographed/videotaped/audio recorded/etc.) as a part of this study.

Please indicate whether you agree for your child to be (photographed/videotaped/audio recorded/etc.) as a part of this study.

* **YES** *(If you change your mind about this at any point, please let the researcher know)*
* **NO**

*If parents/guardians have the option to choose whether or not their child’s names are used when data from this study are published, include (revising as necessary) otherwise delete:*

Please indicate whether you agree to have your child’s full name used in the final (publication/presentation/essay/etc.) that result from this research.

* **YES** *(If you change your mind about this at any point, please let the researcher know)*
* **NO**
* **ALTERATION:**

 ***Name or pseudonym to be used:*** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Printed Name of Minor Minor’s Date of Birth

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Signature of Parent or Legal Guardian Date

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Printed Name of Parent of Legal Guardian

**Once you sign this form, you will receive a copy of it to keep and the researcher will keep another copy.**