**Informed Consent, Assent, and Implied Consent Guidelines**

 An essential aspect of protecting human subjects is that participants and/or their guardians understand the purpose of the research, any risks they might encounter, and the extent of time and effort required. Hence, some type of informed consent, informed assent, or implied consent form will be needed. The degree of completeness and formality of the consent or assent forms may vary depending on factors such as risk and time commitment. The default is to follow the informed consent, parental consent, and child assent form guidelines as described in this document.

 In cases where there is no risk, time commitment is low, and results are anonymous, a more informal approach (implied consent) may be acceptable. If you think implied consent may be sufficient for your research, discuss that possibility with your chair. Examples of low risk survey, interview, and focus group invitations utilizing implied consent are provided in this document. In these cases, voluntary participation is assumed to be evidence of implied consent.

 This document contains the following materials:

* Informed consent form checklist for adults
* Overview of parental consent and child assent forms
* Wilmington University parental consent form outline
* Wilmington University assent form outline
* Sample invitations for low risk surveys, interviews, and focus groups

**Informed Consent Form Checklist for Adults**

|  |  |
| --- | --- |
| **Purpose/Description of the Research**  |  |
| Introduction of the researcher (*My name is \_\_\_ and I am a \_\_\_\_ at Wilmington University. This research is being conducted by…*). |  |
| Clear explanation of the purpose of the research. |  |
| **Participant Recruitment/Involvement** |  |
| Description of participant recruitment strategy, eligibility requirements, and selection process.  |  |
| Description of where the research will take place. When applicable, include documentation of approval from research site. |  |
| State the total number or approximate range of participants in the study.  |  |
| Description of procedures and activities in which the participants will be involved.  |  |
| For surveys and interviews, provide a list of topics that will be discussed.  |  |
| Provide an estimated time required for participant involvement for the entire study. |  |

|  |  |
| --- | --- |
| **Risks & Benefits** |  |
| Description of any possible risks to the participant. If risk is involved, please describe how the researcher will minimize the risks. If no risk is involved, please provide a statement reflecting that.  |  |
| Description of any possible benefits to the participant. If no benefits are involved, please provide a statement reflecting that.  |  |
| **Participants’ Rights** |  |
| Statement that participation in the study is voluntary and participants may withdraw from the study with no penalty or loss of privileges.  |  |
| Statement that participant can refuse to answer any questions without penalty or loss of privileges.  |  |
| **Confidentiality & Data Collection/Storage/Analysis**  |  |
| Statement that data will be kept either confidential (no names disclosed) or anonymous (researcher will not know the name of participants). |  |
| Description of how the data will be kept confidential (e.g. pseudonym or identification information). |  |
| Statement of how data will be stored securely (e.g. locked file cabinet, password protected files/computer).  |  |
| Statement of how long the data will be kept (e.g. minimum of 3 years after the research was completed). |  |
| Statement of how the data will or will not be shared with others (e.g. teachers, school district, etc.).  |  |
| Description of who will have access to the data.  |  |
| Description of how data will be analyzed (e.g., group or individual level) and where they will be reported (e.g., dissertation, publication, etc.).  |  |
| Explanation that the participants will be audio or video recorded and/or transcribed. (If applicable)  |  |
| **Contact Information** |  |
| Contact information for the researcher.  |  |
| Contact information for faculty advisor.  |  |
| Contact information for the University’s Human Subjects Review Committee. |  |
| **Participant Signature** |  |
| Provide a line where participants can indicate consent or lack of consent to participate.  |  |
| Provide two copies of consent form. Researcher collects one; one is given to the participant.  |  |
| For multiple page forms, include the title of the study on each page of the consent form. |  |
| For multiple page forms, include “page \_\_\_ of \_\_\_” formatting.  |  |
| In multiple page forms, provide space on each page for participant to initial indicating that s/he has read each page. |  |

**Overview of Parental Consent and Child Assent Forms**

(These guidelines were developed by the University of Wyoming and have been adopted by Wilmington University’s Human Subjects Review Committee.)

The Human Subjects Review Committee (HSRC) must determine that adequate provisions have been made for soliciting the assent of children, when in the judgment of the HSRC the children are capable of providing assent. The HSRC recommends that assent be sought for children ages seven and older, but may be appropriate for younger children depending on their aptitude.

The HSRC may determine that assent is not a necessary condition for proceeding with the research if:

1. The aptitude of some or all of the children is so limited that they cannot reasonably be assented (determinations of capacity to assent will be assessed by age, maturity, and psychological state, and may be made for one, some, or all children in the research as the HSRC deems appropriate);
2. The intervention or procedure involved holds out a prospect of direct benefit that is important to the health or well being of the children and is available only in the context of research; or
3. The research meets the required criteria for waiver of consent stated in 45 C.F.R. 46.116(d).

When assent is required, the child will sign the assent form for documentation.

In addition to the children’s assent, the principal investigator (PI) is required to solicit consent of each child’s parents, adoptive parents, or guardians.

Parents must be consented following the criteria outlined above and any additional elements the HSRC deems necessary. One parent’s signature is sufficient for research that is minimal risk or greater than minimal risk with the prospect of direct benefit to the participant.

**Wilmington University Parental Consent Form Outline**

**I. General purpose of the study:**

 Why are you conducting this study? What do you hope to gain from this study? Why should children participate?

 **Include a statement such as:** You are being asked to allow your child to take part in a research study. This document has important information about the reason for the study, what your child will do if you approve participation in this research study, and the way we would like to use your child’s information

**II. Procedure:**

 **How and where** will the study be conducted? **Who** will be conducting the study? **What** will the child be expected to do? **How much** of the child's **time** is needed?

**III. Disclosure of risks**

State why risks involved in participation are minimal, or if the project involves more than minimal risk, **describe in detail all potential risks of the study, and procedures to minimize risks.**

**IV. Description of benefits:**

 List any direct/indirect benefits to the child, including compensation or incentive, if any.

**V. Confidentiality:**

 What level of confidentiality will be afforded to subjects? **How will confidentiality be protected? Who will have access to the data, how will the data be protected, and how long will the data be kept?** Will the data be used for research purposes at any time other than the purpose(s) stated above? Please note that confidentiality cannot be guaranteed, but you can describe the methods you will use to protect confidentiality. Confidential and anonymous are not the same, please use the applicable terminology for your study.

**VI. Freedom of consent:**

 **Include a statement such as:** "Your child's participation is voluntary and your child's refusal to participate will not involve penalty or loss of benefits to which your child is otherwise entitled, and your child may discontinue participation at any time without penalty or loss of benefits to which your child is otherwise entitled."

 **For studies involving classroom students:** "Your child's refusal to participate or your child's withdrawal at any point will not affect your child's course grade or class standing." **Include procedures** for the child, or parent/guardian on behalf of the child, **to withdraw** from study.

**VII. Questions about the research:**

 Include name and phone numbers where principal investigator, the faculty advisor, and a HSRC member can be reached during normal business hours.

**VIII. Parental consent required for all subjects under 18 years of age.**

Parental consent must include all the elements of a normal consent form and must be **SEPARATE** from the minor’s assent (the minor and parent need to consider participation independently).

 *PARENTAL SIGNATURE EXAMPLE*:

As parent or legal guardian, I hereby give my permission for (child’s name) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ to participate in the research described above.

 (printed name of participant)

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

 Printed name of parent/legal guardian

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

 Parent/legal guardian signature Date

**IX. If any part of the study is audio or video recorded include**: a check-box or signature line for consent to be audio and/or video recorded.

**Wilmington University Assent Form Outline**

**I. General purpose of the study:**

 My name is (insert the name of the person that will approach the child during the assent process). I want to tell you about a research study I am doing. A research study is usually done to find a better way to treat people or to understand how things work. In this study, I want to find out more about (insert purpose of study in simple language).

**II. Procedure:**

 **How and where** will the study be conducted? **Who** will be conducting the study? **What** will the subject be expected to do? **How much** of the subject's **time** is needed? Describe procedures in words a child in this age group would know and understand.

**III. Disclosure of risks**

State why risks involved in participation are minimal, or if the project involves more than minimal risk, **describe in detail all potential risks of the study, and procedures to minimize risks.**

**IV. Description of benefits:**

 List any direct/indirect benefits to the subject, including compensation or incentive, if any.

**V. Confidentiality:**

 What level of confidentiality will be afforded to subjects? **How will confidentiality be protected? Who will have access to the data, how will the data be protected, and how long will the data be kept?** Will the data be used for research purposes at any time other than the purpose(s) stated above? Please note that confidentiality cannot be guaranteed, but you can describe the methods you will use to protect confidentiality. Confidential and anonymous are not the same, please use the applicable terminology for your study.

**VI. Freedom of consent:**

 **Include a statement such as:** "My participation is voluntary and my refusal to participate would not involve penalty or loss of benefits to which I am otherwise entitled, and I may discontinue participation at any time without penalty or loss of benefits to which I am otherwise entitled."

 **For studies involving classroom students:** "I understand that my refusal to participate or my withdrawal at any point will not affect my course grade or class standing." This statement should be written in language appropriate for the age and level of education of the subjects.

 **Include procedures for the child to withdraw from the study.**

**VII. Questions about the research:**

 Include name and phone number where principal investigator, faculty advisor, and a HSRC member can be reached during normal business hours.

**VIII. Assent to participate**:

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

 Printed name of participant

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

 Participant signature Date

**IX. If any part of the study is audio or video recorded include**: a check-box or signature line for consent to be audio and/or video recorded.

**INVITATION TEMPLATES FOR IMPLIED CONSENT**

When 1) there is very low risk that the data being collected would be sensitive or would harm research participants, and 2) no participant names or identifying information are being included in the report, it is not necessary to have a consent form. Instead, potential participants are sent invitations that provide information about the study purpose and procedures and participant protections. After a person has read the invitation, proceeding to participate is an indication of implied consent. It is not necessary to get signatures.

This document includes templates for three data collection approaches: surveys, interviews, and focus groups. Students conducting low risk research are encouraged to use the relevant template as a starting point for developing an invitation. Each template contains the minimum information that is required to ensure that participants are adequately informed. Students may add further information or modify the language as appropriate.

Please note that it is sufficient to describe the topic of your research at a fairly high level. It is not necessary to provide the title of your dissertation. The topic description should provide enough information to persuade a person that participation is worthwhile but should not reveal the researcher’s agenda, as that could introduce bias.

**SURVEY INVITATION TEMPLATE**

(Salutation)

My name is \_\_\_\_\_\_\_\_\_\_\_\_\_, and I am in a doctoral program at Wilmington University. I am studying \_\_\_\_\_\_\_\_\_\_\_\_\_. I would appreciate your help with my study by taking a short survey about this important topic. The survey should not take more than \_\_\_ minutes to finish. The study results may be published, but your name and anything that might identify you will not be made public.

Choosing to take the survey is voluntary. You may skip any question you do not want to answer and may stop the survey at any time. I hope that you will take a few minutes to answer all the questions to help us better understand \_\_\_\_\_\_\_\_\_\_\_\_\_.

If you have any questions, please feel free to contact me at (wilmu email) or my research advisor, (name), at (wilmu email).

Thank you,

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

**INTERVIEW INVITATION TEMPLATE**

(Salutation)

My name is \_\_\_\_\_\_\_\_\_\_\_\_\_, and I am in a doctoral program at Wilmington University. I am studying \_\_\_\_\_\_\_\_\_\_\_\_\_. I would appreciate talking with you about this important topic. The interview would take place at a time and in a format (in-person, video, or phone) that is convenient for you. The interview is expected to take around \_\_\_ minutes, and it will be (specify audio and/or video) recorded. (If relevant, comment on anyone else who would be involved in the interview and/or transcription.) The study results may be published, but your name and anything that might identify you will not be made public.

Choosing to be interviewed is voluntary. You may skip any question you do not want to answer and may stop the interview at any time. I hope that you will be willing to help us better understand \_\_\_\_\_\_\_\_\_\_\_\_\_.

If you have any questions, please feel free to contact me at (wilmu email) or my research advisor, (name), at (wilmu email).

Thank you,

Note to researchers: Don’t offer to share the transcripts.

**FOCUS GROUP INVITATION TEMPLATE**

(Salutation)

My name is \_\_\_\_\_\_\_\_\_\_\_\_\_, and I am in a doctoral program at Wilmington University. I am studying \_\_\_\_\_\_\_\_\_\_\_\_\_. I would appreciate your participation in a focus group discussing this important topic. The focus group will take place at a time and in a format (in-person, video, or phone) that is convenient for participants. The focus group is expected to take around \_\_\_ minutes, and it will be (specify audio and/or video) recorded. (If relevant, comment on anyone else who would be involved in the focus group and/or transcription.)

The study results may be published, but your name and anything that might identify you will not be made public. I will instruct all focus group participants to keep the discussions confidential but can not guarantee they will do so.

Choosing to participate in the focus group is voluntary. You may skip any questions you do not want to answer and may stop participating in the focus group at any time. I hope that you will be willing to help us better understand \_\_\_\_\_\_\_\_\_\_\_\_\_.

If you have any questions, please feel free to contact me at (wilmu email) or my research advisor, (name), at (wilmu email).

Thank you,

Note to researchers: Don’t offer to share the transcripts.