**William Paterson University Institutional Review Board**

**Parent/Guardian Permission and Child Assent Form Templates**

**Message from WPU IRB to Researchers:**

***BLUE*** *text represents suggestions and information about the consent/assent process from WPU IRB and should be edited out.* ***YELLOW*** *highlighted text is tailored for your study.*

***BLACK*** *text is standard and must be kept in the final consent form copy.*

**Consent Requirements for Research Involving Children under the Age of Eighteen.**

Children are individuals who have not attained the legal age to consent to treatment or procedures involved in a research project. Children are also considered a vulnerable population and additional precautions must be taken to ensure their protection as participants in research projects. Such precautions include obtaining permission from their parents or guardians and the assent of the child.

*Permission* means the agreement of a parent/guardian to a child’s participation in the research.

*Assent* means a child’s affirmative agreement to participate in research. Mere failure to object to participating may not be construed as assent.

Both permission and assent require that investigators provide adequate information about the project to allow for an informed decision to be made. (Federal regulations outline specific criteria that must be addressed in informed consent forms, and this same information must be provided to the parents/guardians when research involves children.)

Permission from a parent/guardian is required before children can be asked for their assent. This permission must be documented by a signed Parent/Guardian Permission Form created from the template provided below.

Once parents/guardians have granted permission for their children to participate in a study, the children may be approached about the study. Regardless of age, children must be told about the research project and given an opportunity to decide if they want to participate. Assent must be documented using an assent form or assent script created from one of the templates below as appropriate based on the age of the children.

Children who choose not to participate, regardless of how quietly they do so, may not be included in the study even if their parents have given permission for them to participate. Investigators must ensure that only children who want to participate are involved and that children who change their minds during their participation have the opportunity to stop at any time. A lack of objection to participation cannot be treated as an individual’s permission, consent, or assent.

**Instructions for Using the Parent/Guardian Permission and Child Assent Templates**

The templates provided ensure that all requirements of Informed Consent are addressed. Prior to finalizing the forms, please delete all instructions. In addition to the instructions in this section, text enclosed in brackets and/or highlighted in yellow should be replaced with text specific to the study being proposed.

Both the Parent/Guardian Permission Form and Child Assent Forms should be written in plain, easy-to-follow language that is appropriate for the subject population. Please note: the text should be readable at an eighth-grade level or below for the Parent/Guardian Permission Form. The assent form should be written in a simpler format with language appropriate to the youngest child in the age range.

Avoid using technical jargon or overly complex terms that may be difficult for someone outside your field of expertise to understand. For information and guidance on using plain language, the Federal government’s [Plain Language](https://www.plainlanguage.gov/) website <https://www.plainlanguage.gov/> is a useful resource.

How to get the Readability Grade Level Score of a Document in Microsoft Word

1. Open Microsoft Word.

2. Click **File** in the upper left-hand corner.

3. Click **Options**.

4. Under Options, click **Proofing**

5. Under heading” When correcting spelling and grammar in Word” select **Show**

**readability statistics**.

6. Click **OK**.

7. Run the Spelling and Grammar check on your document.

8. The ‘Editor’ pane will open on the right side of the screen. Select **Insights.**

9. Word will present the Readability Statistics box. Toward the bottom of the box is the Flesch-Kincaid Grade Level Score.

***Parent/Guardian Permission***

The Parent/Guardian Permission form is a modified version of an informed consent document and is written in the third person to indicate that the individual granting permission is not the individual whose participation is sought. In cases where the parent will be a participant in the same study, he or she should sign both an informed consent form for his or his own participation and a permission form for the child’s participation.

***Assent of Children under the age of 7***

Investigators are required to provide to the IRB information about how they will ensure children want to participate, are not upset during their participation, and understand that they have the right to stop their participation at any time. Children in this age group should be used only when they are the only available source of the data needed for a project. Investigators are required to submit to the IRB a description of the verbal assent process to be used, including how assent will be documented, and a script of information that will be verbally provided to the children.

***Assent of Children ages 7-12***

Children ages 7-12 are generally capable of making a decision about whether they want to participate in a research project and should sign an assent document before their participation begins. If the child does not know how to sign their name in cursive, they can try their best to sign, or print their name instead.

The assent document should be no more than one page in length and, in simple terms, (1) explain what the research is about; (2) describe why the child is being asked to participate; (3) identify what the child will be asked to do; (4) let the child know that participation is entirely voluntary and that he or she may stop at any time; and (5) disclose any risks and potential benefits.

For projects involving no more than minimal risk, the IRB may elect to allow verbal assent to be used with children ages 7-12 when appropriate. Investigators requesting approval to use verbal consent with this age group are required to submit to the IRB a justification for the use of verbal consent; a description of the verbal assent process to be used, including how assent will be documented; and a script that will be provided verbally to the children.

***Assent of Children over the age of 12***

Children between the ages of 13 and 17 are generally capable of assenting to participate in a research project and should sign an assent document before their participation begins. The assent document must be written in language understandable to the children, (1) explain what the research is about; (2) describe why the child is being asked to participate; (3) identify what the child will be asked to do; (4) let the child know that participation is entirely voluntary and that he or she may stop at any time; and (5) disclose any risks and potential benefits.

**William Paterson University**

**Parent/Guardian Permission for a**

**Child/Dependent to Participate in a Research Study**

**Title of Study**

**Principal Researcher:**

**Other Researchers:**

**Faculty Advisor Name and Department:**

**Faculty Advisor Email and Phone Number:**

**Protocol Approval Date:**

**Protocol Number:**

**Key Information**

Your child/dependent is being invited to participate in a research study. This document includes important information you should know about the study. Before providing permission for your child/dependent to participate, please read this entire document and ask any questions you have.

**Does my child or dependent have to participate?**

Your child or dependent does not have to be in this study. If you decide to permit your child/dependent to take part in the study, it should be because you want to allow him or her to volunteer. Your permission allows us to ask your child/dependent to participate, but he or she does not have to participate, even if you grant permission.

Your child/dependent will not lose any benefits or rights he or she would normally have if you choose not to grant permission or if your child/dependent chooses not to participate. Your child/dependent can stop at any time during the study and still keep the benefits and rights he or she had before volunteering.

If you decide to grant permission for your child/dependent’s participation and your child/dependent chooses to participate, he or she will be one of about [add number of expected participants] people in the study.

**What is the purpose of the study?**

(Describe the study’s purpose briefly and clearly. Do **NOT** use any jargon or technical language. Make sure you state the purpose of the research.)

The purpose of the study is to [add description of study’s purpose.] If there is a condition or circumstance that makes the child/dependent eligible for the study, specify this information. By doing this study, we hope to learn [explain what you hope to learn from the study].

**Where is the study going to take place and how long will it last?**

The research procedures will be conducted at [add location]. The study will take about [give the amount of time in minutes or hours and/or days. If the study has different sessions, list how long each session will last.]

**What will my child/dependent be asked to do?**

In this section, tell the parent/guardian what to expect during the child/dependent’s participation in the study. Describe all procedures in lay language, using simple terms and short sentences or bullet points. If the study involves numerous procedures and/or visits, give a timeline description of the procedures that will be performed. If the study involves procedures that are experimental, identify them as such.

(Clearly list what the participants will experience, in chronological order. Do **NOT** use any jargon or technical language.)

i.e.,

* Your child’s hearing will be evaluated, if she/he falls into the normal hearing range, we will proceed with these steps.
* Your child will be fitted with headphones and asked to listen to a tape of three individuals speaking for 5 minutes.
* Your child will then complete a 20-question survey on what she/he heard.

If applicable, provide a lay description of the randomization procedures and describe the chances of the child being assigned to any one group.

If applicable, identify the procedures being performed as part of the care or services the child would normally receive separately from the research procedures.

**Are there reasons why my child/dependent should not take part in this study?**

State in basic lay language reasons a child could be excluded from volunteering, such as being over or under a certain age.

**What are the possible risks and discomforts?**

Describe foreseeable risks or discomfort to participants, including physical, psychological, emotional, social, criminal, or civil liability, employability, reputation risks, economic or financial harm. (e.g., breach in confidentiality in sensitive research).

*If the research involves minimal risk to the subjects, include the following statement:*

To the best of our knowledge, the things your child/dependent will be doing have no more risk of harm or discomfort than he or she would experience in everyday life.

*If the research involves any procedures that could cause possible emotional or mental harm or discomfort, include the following statement and a list of resources:*

Although we have made every effort to minimize this, your child/dependent may find some questions we ask (or some procedures we ask him or her to do) to be upsetting or stressful. If so, [include text that appropriately relates and list the resources].

*If you are collecting data using the internet and/or email, include the following.* Data will be collected using the Internet; we anticipate that your child/dependent or dependent’s participation in this presents no greater risk than everyday use of the Internet. Please note that email communication is neither private nor secure. Though we are taking precautions to protect your child/dependent or dependent’s privacy, you should be aware that information sent through email or internet could be read by a third party.

**What are the benefits of taking part in this study?**

Your child/dependent or dependent may benefit from this study [describe foreseeable benefits to the participant if relevant. If there are no benefits to the participants, state explicitly, “There are no benefits to your child/dependent for being in this study.”] Others may benefit from this study [include the benefits to your field of study].

**If my child/dependent doesn’t take part in this study, are there other choices?**

If your child/dependent does not participate in the study, there are no other choices except to not take part in the study.

[OR]

If your child/dependent does not participate in this study, there are other choices, including [Describe choices for other procedures in which the subject could participate to receive the same level of benefit].

**Other Important Details**

**Who is doing the study?**

The person in charge of this study is [add name of principal investigator] at William Paterson University. If the PI is a student, add the following statement: They are being guided in this research by [add Faculty Research Advisor Name]. There may be other people on the research team assisting at different times during the study.

**What will it cost for my child/dependent to participate?**

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

[OR]

[Describe any costs the parent/guardian may incur as result of the child/dependent participating in the study. For example: Parents/guardians may have to pay for the cost of getting to the study site and a parking fee.]

**Will my child/dependent receive any payment or reward for taking part in the study?**

Your child/dependent will not receive any payment or reward for taking part in this study.

[OR]

To compensate you for the time your child/dependent or dependent spent in this study, the participant will receive (describe compensation). (State whether participants will be eligible for compensation if they withdraw from the study prior to its completion. If compensation is pro-rated over the period of the participant's involvement, indicate the points/stages at which compensation changes during the study.)

**Who will see the information my child/dependent gives?**

Your child/dependent’s information will be combined with information from other people taking part in the study. When we write up the study to share it with other researchers, we will write about this combined information. Your child/dependent will not be identified in these written materials.

[If the study is anonymous:]

This study is anonymous. That means that no one, not even members of the research team, will know that the information your child/dependent give came from your child/dependent.

[If the study is not anonymous:]

We will make every effort to protect your child’s privacy. Data that could identify your child will be kept separate from the data we report in a secure place. All paper materials will be stored in\_\_\_\_\_\_\_ (a locked, secure place). Computer data will be stored in a \_\_\_\_\_\_ (password-protected database). Parental Permission Forms and assent forms will be \_\_\_\_\_\_\_\_\_ (stored in a locked, secure place).

However, there are some circumstances in which we may have to show your child/dependent’s information to other people. These circumstances include:

1. A federal, state, or local law requires disclosure, such as information about suspicion of child abuse or neglect.
2. Your explicit approval for the researchers to release personally identifiable information.

If focus groups:]

Although the researchers will take every precaution to maintain confidentiality of the data, the nature of focus groups prevents the researchers from guaranteeing confidentiality. The researchers would like to remind participants to respect the privacy of fellow participants and not repeat what is said in the focus group to others.

If the study involves the collection of identifiable private information or identifiable biospecimens, include one of the following two statements as appropriate:

The information or biospecimens your child/dependent provides as part of the research will not be used or distributed for future research studies even if identifiers are removed.

[OR]

Identifiers may be removed from the identifiable private information or identifiable biospecimens your child/dependent provides as part of the study. After such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

**What if my child or dependent no longer wants to participate in the study?**

If your child/dependent decides to take part in the study, he or she will still have the right to decide at any time that he or she no longer wants to participate. Your child/dependent will not be treated differently if he or she decides to stop taking part in the study.

**What happens if my child or dependent gets hurt or sick during the study?**

[Include this question if the risk level of the study is a greater than minimal risk.]

[Remove if the study is a minimal risk study.]

**What if I have questions?**

If you have questions about the study, you can contact [Principal Investigator’s name, phone number, and email address and Faculty Sponsor’s Investigator’s name, phone number, and email address.]

If you have any questions about your child/dependent’s rights as a research volunteer, you can contact the IRB Administrator at William Paterson University at 973-720-2852 or IRBAdministrator@wpunj.edu.

One copy of this consent form is for you to keep.

**What else do I need to know?**

*If applicable, disclose what institutions or companies are involved in the study through funding or cooperative research or by providing supplies or equipment. If not applicable, remove this section.*

**Permission**

If you would like to give permission for your child/dependent or dependent to participate in this study, please read the statement below, write your name and your child/dependent’s name, and sign.

*I have thoroughly read this document, understand its contents, have been given an opportunity to have my questions answered, and give permission for my child/dependent to participate in this study if he/she chooses to participate.*

***When the investigator is audiotaping, videotaping, or photographing participants, add the following:***

As part of this study,it is okay to (audiotape, videotape, or photograph – include only process(es) pertinent to your study) my child/dependent or dependent:

Please initial: Yes No

Parent/Guardian’s Name Date Child/Dependent’s Name Date

Parent/Guardian’s Signature Date

**Participant Assent Script**

(for children under the age of 7)

**Title of Study**

I want to tell you about a research study I am doing. A research study is a way to learn more about something. I would like to find out more about [explain your study in simple terms]*.* You are being asked to join the study because [explain why the child is being asked to participate].

If you agree to join this study, you will be asked to [explain what you will ask the child to do.]

[Insert language for risk and potential benefits, if applicable.] *Example text is below, please delete and replace.*

There may be times during the research study that you may feel frustrated, but that is okay. Just let me know and we can take a break.

I expect that the study will help you become a better reader. I may learn something that will help other children become better readers.

You do not have to join this study. It is up to you. You can say okay now. You can also say no. If you say okay and then you change your mind later and want to stop, then all you have to do is tell me or your parents you want to stop. No one will be mad at you if you don’t want to be in the study or if you join the study and then change your mind later and stop.

Before you say yes or no to being in this study, we will answer any questions you have. If you join the study, you can ask questions at any time. Just tell me that you have a question.

I will also talk to your parents about this study. You can talk this over with them before you decide.

Would you like to be in this research study?

*End of verbal script*

*----------------------------------------------------------------------------------------------------**--------------*

TO BE COMPLETED BY PERSON OBTAINING VERBAL ASSENT FROM THE CHILD:

Child’s response:

 Yes, I will be in this research study. No, I don’t want to do this.

Child’s Name (printed)­­ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Name (printed) and Signature of Individual Obtaining Assent Date

**Assent Form for Child’s Participation in a Research Project**

(for children between the ages of 7 and 12)

**Title of Study**

I am conducting research about [explain your study in simple terms] and would like to ask for your help because [explain why the child is being asked to participate]. If you decide to participate in this project, I will ask you to [explain what you will ask the child to do].

Your parents know that I am asking you if you want to participate, but it is up to you to decide if you want to do this. You should not feel like you have to participate, and no one will be upset with you if say no. Even if you say yes now but decide you want to stop later, no one will be upset with you. All you have to do is tell me that you want to stop.

Insert language on risks and potential benefits, if applicable.

*If you want to participate, you can write your name on the line below. If you have any questions, please ask me before you write your name. If you do not want to participate, please do not write your name.*

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

Child’s Name or Signature (If able) Date

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

Name (printed) and Signature of Individual Person Obtaining Assent Date

**Assent Form for Minor’s Participation in a Research Project**

(for minors between the ages of 13 and 17)

**Title of Study**

You are being invited to participate in a research study about [add description of study’s purpose]. We would like to ask for your help because [explain why the child is being asked to participate]. If there is a condition or circumstance that makes the potential subject eligible for the study, specify this information.

This document includes important information you should know about the study. Before deciding whether you want to participate, please read this entire document, and ask any questions you have.

**What will I be asked to do?**

If you decide to participate, you will be asked to [add a description to tell the child what he or she will be expected to do while participating in the study].

**Do I have to participate?**

Your parents know that we are asking you if you want to participate, but it is up to you to decide if you want to do this. You should not feel pressured to participate, and you have the right to choose not to participate. You will not lose any rights or benefits you would normally have if you chose not to participate. If you agree to participate now and decide later that you want to stop, all you have to is tell the researchers, and they will allow you to stop. You will still keep the rights and benefits you had before volunteering.

**What will I get for participating?**

You will receive [describe the reward] for taking part in this study. If you have to quit before the study is finished, the payment will be based on the amount of time you are in the study.

**[OR]**

You will receive [describe the reward] for taking part in this study. If you should have to quit before the study is finished, you will still receive [the full amount, gift card, prize, etc.].

**[OR]**

You will not receive any payment or reward for taking part in this study.

**Who will see the information I give?**

Your information will be combined with information from other people taking part in the study. When we write up the study to share it with other researchers, we will write about this combined information. You will not be identified in these written materials.

[IF THE STUDY IS ANONYMOUS:]

This study is anonymous. That means that no one, not even members of the research team, will know that the information you give came from you.

[IF THE STUDY IS NOT ANONYMOUS:]

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. For example, your name will be kept separate from the information you give, and these two things will be stored in different places under lock and key.

**Can my taking part in the study end early?**

If you decide to take part in the study, you still have the right to decide at any time that you no longer want to participate. You will not be treated differently if you decide to stop taking part in the study.

The individuals conducting the study may need to end your participation in the study. They may do this if you are not able to follow the directions they give you, if they find that your being in the study is more risk than benefit to you, or if the agency funding the study decides to stop the study early for a variety of scientific reasons.

**Is there anything else I need to know?**

Explain any potential risks or benefits, if applicable.

**What if I have questions?**

Before you decide whether you want to participate, please ask any questions that come to mind now. Later, if you have questions about the study, you can contact the investigator, [add principal investigator’s name] at [add phone number or email address]. We will give you a copy of this form to take with you.

If you would like to participate, please read the statement below and print and sign your name.

*I have thoroughly read this document, understand its contents, have been given an opportunity to have my questions answered, and have decided that I would like to participate in this study.*

Minor’s Name Minor’s Signature Date

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

Name (printed) and Signature of Individual Obtaining Assent Date