

CHILD ASSENT & PARENT CONSENT INSTRUCTIONS & SAMPLES

IMPORTANT: The instructions and sample forms in this document are to be used in studies involving participants under the age of 18. For participants aged 18 or older, use the Adult Consent forms and instructions at <https://provost.umw.edu/irb/instructions-and-forms/>. (For biomedical research and/or use of existing biomedical data, consult with the IRB chair.)

Informed consent procedures are required for research involving human subjects. Appropriate parental consent and child assent forms must be submitted with IRB applications.

Submit the Consent and Assent forms with your IRB application to the appropriate IRB member for your department as listed at <https://provost.umw.edu/irb/board-members/>. To avoid delays, ensure that the information on the Consent and Assent forms is consistent with information on the IRB application form. Subsequent **changes to the consent/assent forms or procedures** after initial IRB approval must be reviewed and approved by the IRB before they can be implemented.

Parental Informed Consent

Informed consent of a **legally authorized representative** (parent, guardian, etc.) is required for participation in research of any children under the age of 18. For research on children who are wards of the state, consult with the IRB chair. In research involving greater than minimal risk, the consent of both parents is required unless one parent is not reasonably available. The parent consent form must be written in language the parent can understand. In general, parental consent must meet the requirements of informed consent, including requirements for translations, as explained on the “Adult Informed Consent Instructions (2019)” at <https://provost.umw.edu/irb/instructions-and-forms/>. If the parent does not voluntarily consent, the child’s assent cannot override the parent’s decision. Similarly, if the child does not voluntarily give assent according to the requirements below, the parent’s consent cannot override the child’s decision.

Waiver of Parental Consent: Only the IRB can waive informed consent. A waiver of parent informed consent can be requested for research with child participants if it is justified in the IRB application, and if appropriate alternative measures are taken to protect the children. For information on obtaining waivers of consent, contact the IRB Chair.

Child Abuse or Neglect

For general purposes, the parental consent form should include wording to the effect that researchers “will not reveal any private information about the child to anyone, unless required by law to do so.” UMW employees are required by Virginia law to report evidence of child abuse or neglect that they discover in their professional capacity. For additional information on these legal obligations, see the UMW policy on [Child Abuse and Neglect Reporting](#).

To protect the child, researchers can request the IRB to waive the requirement for consent of a parent or guardian. This could be justified in studies likely to elicit information about child abuse or neglect, as well as other instances in which parental permission would jeopardize the child’s welfare or compromise the child’s rights. In such cases the request for a waiver of consent should include a reasonable argument that:

- informing parents/guardians may result in harm to the child, or
- parental/guardian permission may not be in the child’s best interest because of conflicts in the parental/guardian role as it relates to the research

For additional information, consult the Office of Human Research Protections [Recommendations Relative to Research Involving Children](#).

Child Assent

Child assent to participate in research is **required, in addition to parental consent**, unless the IRB waives the assent requirement. As long as parental consent is obtained, the IRB can waive child assent in any of the following circumstances described at [45 CFR 46.408\(a\)](#):

- a) The capability of some or all of the children is so limited that they cannot reasonably be consulted. As a general rule of thumb, the IRB considers child participants aged 7 (second grade) and older capable of giving assent.
- b) The intervention or procedure involved in the research holds out the prospect of alleviating a serious problem affecting the health or well-being of the children and is available only in the context of the research.
- c) The IRB may waive the requirement of child assent under the same conditions as those for waiver or alteration of informed consent in research involving adults (see “Instructions for Consent Waivers or Alterations” at <https://provost.umw.edu/irb/instructions-and-forms/>)

Child Assent Form: The form should be written in language the child can understand (see Sample Assent Form below). For children with potential reading difficulties, the written consent document **may be read aloud exactly as written** and approved by the IRB. If the child participants are of varying ages, it is appropriate to submit different versions of the form. The child’s decision on the assent form must be honored; it cannot be disregarded in favor of the parent’s consent.

Avoiding Undue Influence: Because children are more vulnerable to persuasion than adults, researchers must take special care for no undue influence during the assent process. This is especially important if the investigator is in a position of authority over the child such as a teacher. Language such as “You will be helping me” or similar **appeals** to their sense of fun, fairness, or obedience should be avoided. Likewise, promises of tempting **rewards** to induce participation should be avoided. Additionally, care should be taken in choosing the **setting** in which children are asked for their assent. For example, if they are asked in the company of other children, they may be subject to peer pressure; and if asked individually by an adult or in the presence of a parent, they may feel pressure to obey. On the IRB application form, researchers should indicate steps to be taken to mitigate these effects.

Educational Settings

If the research involves **experimental and control groups**, participants in both groups must have parental consent and child assent in order for data to be collected from them. An experimental research design should never withhold instruction that the child is entitled to. The IRB will look closely at research in which one group of students receives instruction different from that of another group, in order to assess whether either group would miss instructional time or receive less effective instruction. For additional guidance, consult the [American Educational Research Association Code of Ethics](#).

Use of education records in research requires adherence to the Family Educational Rights and Privacy Act (FERPA) and to other relevant federal and state laws. FERPA relates to use of private student records such as grades and disciplinary actions. IRB procedures for informed consent are not sufficient permission for use of FERPA-protected records in research. A convenient guide to FERPA is available from the [U.S. Department of Education website](#). **It is the responsibility of the researchers** and of the officials of the school division that holds the records to ensure that these laws are adhered to. However, the IRB may require researchers to document that they have taken appropriate measures to comply with these laws. Teachers who have access to student records in their role as teachers should **consult with the appropriate school officials** before using the records for research purposes. For research involving student records maintained by UMW, consult with the Associate Provost for Institutional Analysis and Effectiveness (<https://academics.umw.edu/iae/>).

Deception

The IRB is not likely to approve deception in research on children unless it finds that the value of the research exceeds the potential negative effects of the deception and that equally effective alternative procedures are not feasible. **Both the child and parents must be debriefed** about the deception, following procedures required on the “Debriefing Form & Instructions” available at <https://provost.umw.edu/irb/instructions-and-forms/>

Recordings and Photographs

If the use of **voice, video, digital recordings or images** of children will be collected during the research, specific permission from both the child and parents is required on the informed consent and assent forms. Recommended wording to obtain this specific permission is provided on the sample forms below. Indicate if written transcripts will be made from recordings. Research on children should not involve the use of covert recording or photographic procedures. If any recordings, or images of children or their work will be used in presentations, publications, or internet archives of the research, parents and children should be informed, and it may be appropriate to have parents sign a release form.

Editing the Sample Forms

The forms provided below are samples and must be carefully edited to describe the specifics of your particular study. These samples pertain to research in educational settings, which is the most common type of study on children conducted by UMW researchers. The **organization and headings** used in the sample Parental Consent Form should be preserved, but you can be more flexible with the sample Child Assent Form. The word “SAMPLE” should be deleted from the title of the forms.

If research participants are UMW students and the **academic department has obtained parental permission** for underage students to participate in department research, then a consent form may be used in place of a child assent form and the participant’s signature line should say: *I certify that I am at least 18 years of age or have a signed parental consent form on file with the _____ Department.*

Parental Consent Recommendations

- The “Brief Description” at the beginning should provide the basic information that the legally authorized representatives would need to guide them in making an informed decision about the child’s participation.
- Parents should be told if the child’s assent will or will not be requested, and if so, that both parent and child agreement are required.
- Give complete, specific details and concrete examples of what children will be expected to do to provide data for the study and how the data will be collected. If an experimental model will be used, both the control and experimental procedures should be described (or use separate consent/assent forms).
- If recordings or photographs will be made of children or their work, the Parental Consent Form should specifically ask for the parent’s agreement. If the recordings or photographs will be used in presentations or publications, it may be appropriate to use a separate release form.
- For research in classroom settings, describe what, if anything, will be expected of students who do not participate. It may be appropriate to include wording such as “Even if your child does not participate in the study, he or she will still receive the required instruction and be expected to complete the required assignments and tests.”

Child Assent Recommendations

- While the information in the Child Assent Form can be less detailed than the information in the Parental Consent Form, children should be given enough information to make their own choice

about whether to participate or not. The basic elements of consent should be present: purpose of the research, risks and benefits, extent of confidentiality, the voluntary nature of participation, the opportunity to withdraw, and the importance of asking questions.

- Unless a waiver of child assent has been approved by the IRB, the assent form should be in writing. The written form may be read aloud to children exactly as written, and this should be indicated in the signature area of the assent form as indicated on the sample below.
- Children should be told that their parent or guardian is also being asked for permission to let them participate, and that if either the child or the parent disagree, the child will not be a participant.
- For research in classroom settings, describe what, if anything, will be expected of students who do not participate, and give assurance that expectations will not be higher for students who do participate.
- If recordings or photographs will be made of participants, the Child Assent Form should specifically ask for the child's agreement.
- Do not exploit your relationship with the child (if any) in the wording of the form. Avoid personalized language such as 'I have to do this research to complete my degree,' or 'I encourage you to take part in this study.'
- Use vocabulary and sentence structure appropriate to the age and educational level of the participants. If the children will be a wide range of different ages, more than one version of assent form should be used.
- Repeating key information in different ways is a good way to increase children's understanding.
- The written form should be read aloud to children with limited reading skills or in case of unidentified reading comprehension difficulties.

SAMPLE PARENTAL INFORMED CONSENT FORM

Brief Description of Research Study

The purpose of the research described below is to investigate how short periods of mild exercise affect children's attention and participation during lessons. During this study children will receive their normal instruction. The only difference will be that at the beginning of their mathematics class they will perform 5 minutes of mild stretching and relaxation exercises. Then during the lessons I will observe the students and keep track of each student's attention and participation. The risks to children in this study are minimal, but the benefits could be improved attention and participation. **Please read the rest of this form before deciding if you will allow your child to be in this research study.**

My name is _____ and I am a student at the University of Mary Washington and the student teacher in your child's seventh grade mathematics classroom. Because you are the parent or legally authorized representative of a child in this classroom, I am seeking your permission to let your child participate in this research study. Involvement in the study is voluntary, so you may decide whether to let your child participate or not. I will also ask your child if he or she wants to be in the study, and I will only collect information if both you and your child agree. Before making your decision, please read the information below and ask me any questions that you have about the research; I will be happy to explain anything in greater detail.

Details of the Child's Involvement

Students in your child's mathematics class will do 5 minutes of mild stretching and flexibility exercises at the beginning of each class over a six week period from _____ to _____ (dates). Students will sit at their desks or stand next to their desks to perform the exercises. Some typical exercises will include reaching high, touching toes, rolling shoulders, stretching fingers, standing on tip-toe, and flexing legs. They will follow along with me during the exercises, and I will play soothing music at the same time. While they are exercising, I will take photographs of those children who agree and have parental permission to be photographed.

After the exercise period, I will teach the regular lesson scheduled for that day. While teaching, I will keep a clipboard chart to mark my observations of how often each child in this study participates in the lesson by asking or answering questions and how often I observe them paying or not paying attention. I will use my observation charts to track how students' participation and attention increase or decrease from the beginning to the end of the 6-week study. Even if your child does not take part in my study, he or she will still be able to do the exercises if they choose and are able, but I will not use any data about their participation and attention in my study. Children who do not participate in the exercises will work in a separate group with the lead teacher during the exercise period.

Privacy and Confidentiality

This study will take place while children are in their classroom, so they will not have privacy during the exercises or while being observed. However, to ensure confidentiality I will not reveal any private information about your child to anyone, unless required by law to do so. My observation records will be in my possession at all times, and only I will know which records go with which child. In any reports I make about this study, I will not use your child's name or any other information that could be used to identify him or her directly or indirectly. The only

exception to this would be if both you and your child agree to let me photograph him or her and use the photographs in my reports of this research. When my study is complete, I will destroy all of the information I collected that identifies individual students.

Risks and Benefits of Participation

The mild exercises that children in this study will do have very minimal risks for children. Some children may experience mild pain up to a day after doing stretching exercises if they are not used to that kind of activity. Because the exercises will be done “in place” with little movement, there is not much chance of injury, but if any children complain of pain I will ensure they are seen by the school nurse, following the normal school procedure.

There are no rewards or extra credit grades for students who take part in this study, and no penalties of any kind if they do not take part. However, being in this research study might have important physical and educational benefits for your child. Research has already shown that regular stretching and relaxation exercises improve blood flow to the brain. Research also indicates that children’s test scores tend to improve as a result of regular physical exercise. If the results of this study show a positive impact on children’s attention and classroom participation, it could improve education for more children in the future.

Participant Rights

You have the right to *ask any questions you have* before, during or after the study, and I encourage you to do so. If you do not want your child to be in this study, there will be no penalties or loss of benefits that he or she is entitled to. If you agree to let your child be in this study and later change your mind, you have the right to take him or her out simply by contacting me at the email address below, and I will destroy any research data collected about your child. This research has been approved by the University of Mary Washington Institutional Review Board, a committee responsible for ensuring that the safety and rights of research participants are protected. For information about your and your child’s rights regarding this research, contact the IRB chair, Dr. _____ name _____ (username@umw.edu).

Contact Information

For more information about this research before, during or after your participation, please contact me (username@umw.edu) or my university supervisor, Dr. _____ name _____ (username@umw.edu). To report any unanticipated problems relating to the research that your child experiences during or following participation, contact my university supervisor, Dr. _____ name _____ (username@umw.edu). **Please return this form to me by _____ (date).**

Before signing this form, please ask me any questions you have about participation in this study.

To be Completed by Participant

I have read all of the information on this form, and all of my questions and concerns about the research described above have been addressed. I choose, voluntarily, to permit my child to take part in this research study. I certify that I am at least 18 years of age.

Print name of child

Print name of parent or legally authorized representative

Signature of parent or legally authorized representative

Date

I understand that my child's participation in this research may involve taking photographs of my child while doing exercises (check all that apply):

I permit my child to be photographed

I permit photographs of my child to be published or presented publically

I **DO NOT** permit my child to be photographed

Signature of parent or legally authorized representative

Date

To be completed by Researcher

I confirm that the legally authorized representative of the child named above has been given an opportunity to ask questions about the study, and all the questions asked have been answered to the best of my knowledge and ability. A copy of this Consent Form has been provided to the child's legally authorized representative, and I will keep the original for a minimum of three years.

Print name of researcher

Signature of researcher

Date

SAMPLE CHILD ASSENT FORM

Dear Student,

My name is _____, and the reason for this letter is to ask if you want to be in a research study I am doing. By “research” I mean that I am trying to find out more about something. In this study I am trying to find out more about how students feel when they work in small groups with other students.

I have already asked your parent or guardian if they will permit you to be in this study. If they did not agree, you will not be asked to sign this form. If they did agree, it is still your choice to make, and I am now going to describe what you will do if you agree to be in this study. I am going to read this information to you, so listen carefully and ask any questions you have before you decide whether to be in the study or not.

What will you do if you are in this study?

During the next four weeks in your social studies class, the lessons will be about the job of the President of the United States. During this unit, all students will work in small groups with other students to study this information and explain it to each other. If you agree to be in my study, you will do the same work as other students and be graded the same way.

At the beginning of the unit on the President, all students in class will take a quiz to see how much they already know about the topic. Then at the end of the unit, all students will take the same quiz again to see how much new information they learned. If you agree to be in my study, I will keep track of your quiz scores to use in my research study.

Also, if you decide to be in my study, I will meet with you individually to ask you questions about your experiences and feelings when working with other students during the group activities. There will be one individual meeting at the beginning of the unit, and another meeting at the end. Each meeting will take about 15 minutes. I will use my computer to make a recording of what you say during each meeting so that I can keep it and see how your thoughts change from the beginning to the end.

What will you do if you are not in this study?

Nothing bad will happen to you if you do not want to be in the study, and it will not hurt your grade in the class. You will still do the group activities and take the quizzes because these are required for the class, but I will not keep track of your scores for my study. Also, if you are not in the study, I will not meet individually with you and will not record what you say about group work. While I am meeting with other students to discuss the study, you will have time for silent reading.

Will anything bad happen to you in this study?

If you decide to be in this study, you will not have any extra work, but you might feel strange about meeting individually with me or having your voice recorded. I will take special steps to make sure that you feel okay during the meeting and with the recording. You do not have to answer any questions during the meeting that you do not want to answer. I will also make sure that you do not miss any instruction that other students get during that time.

Will anything good happen to you in this study?

You will not receive any special rewards or extra credit points for agreeing to be in this study. In other research studies like this, some students did better in class because they talked

about and thought about their group work experiences, and this might or might not happen for you.

Will anyone else know what you do or say in this study?

In my study, I will not use the names of any students. If you decide to be in this study, I will not tell anyone else about what you say during your individual meetings with me, unless I have to for legal reasons.

What if you have any questions?

Be sure to ask me any questions you have before deciding whether to be in this study or not. Even if you don't have questions now, you can ask me about this study at any time later. If you would like time to discuss it with your parents before making your decision, please tell me.

What if you change your mind?

If you decide to be in this study and later change your mind, just tell me that you want to stop. I will stop collecting information about you for my study and will take out all of the information I already have about you. I will finish my study on _____ (date), so that is the deadline when you should tell me if you want your information taken out of the study.

Print name of researcher

Signature of researcher

Date

To the Student: Your signature below indicates that you have read the information on this form [or that I have read the information on this form aloud to you], and that all of your questions about this research study have been answered.

Please put an X next to your decision:

____ I agree to take part in this research and I will let you make a recording of what I say

____ I DO NOT want to have any information about me used in this research

Print name of student

Signature of student

Date