**REMINDER: Delete all guidance text found in red BEFORE IRB submission. The Consent Form is written speaking to the parent/guardian of the child study participant; the Assent Form is directed towards the child participant. The Consent and Assent should be written in 2nd person language (“you” statements) that is straightforward and easily understandable for the age, cultural background, and mental capacity of your intended participants. Consents for adults should generally be written at an 8th grade reading level; Assents must be written in language that the youngest subject can understand. You may use multiple Assents for different age groups of child participants as needed.**See OHRP for more helpful guidance: <http://www.hhs.gov/ohrp/policy/ictips.html>.

**KEEP THE CONSENT AND ASSENT FORMS CONCISE, BRIEF, AND CLEAR.** Try to focus on what is important to the participant(s) in making a decision about whether or not to participate.

**CONSENT FOR PARENT / GUARDIAN**

**TITLE OF RESEARCH PROJECT**

Enter the project title – it **must** match the title used in your online IRB protocol submission.

 **RESEARCH TEAM**

Provide the name, department, and contact details of the Principal Investigator (PI). If you are a student PI, also include the name, department, and contact information of your faculty advisor. Listing other research team members is optional and not recommended for protocols with frequent personnel changes, as this will necessitate modification submissions.

**IMPORTANT INFORMATION ABOUT THIS RESEARCH PROJECT**

The research team above is conducting a research study about \_\_\_. Provide an explanation of the purposes of the research in simple, non-technical language; **Ex**: “The purpose of this research is to determine whether or not performing different exercises two times a week may help children with Developmental Coordination Disorder (DCD) improve their motor and coordination skills.” Or “This study is being done to help us better understand the experiences of children who live in single-parent households.” You and your child can choose to participate in this research study if [you are / your child is] [explain the study inclusion & exclusion criteria briefly here, **i.e**. “between 7 and 13 years old and has been previously diagnosed with DCD by a medical doctor,” or “between 6 and 10 years old and has been living with only one parent for at least six months.”]

You might want to allow your child to participate in this study if you (explain reasons why a parent or child might want to participate, such as “if you would like to help researchers learn whether these exercises are effective in improving coordination skills in children with DCD,” or “if you would like to give your child a chance to talk with trained social workers about what it feels like to live in a single parent household.”) However, you might not want to allow your child to participate in this study if you or your child (explain reasons why someone might reasonably not want their child to participate, such as “if you are afraid that your child will be injured while he/she participates in the physical exercise activities,” “if you feel uncomfortable allowing your child to participate in a recorded interview without you present in the room,” or “if you do not have the time to bring your child to two 3-hour study visits on the UT Arlington campus.”)

This study has been reviewed and approved by an Institutional Review Board (IRB). An IRB is an ethics committee that reviews research with the goal of protecting the rights and welfare of human research subjects. The most important right for potential research participants is informed consent. You and your child should both take your time to consider the information provided by this consent form and the research team, and ask questions about anything either of you do not fully understand before making a decision to participate.

**TIME COMMITMENT**

Explain how many study visits, interactions, or follow ups are expected for each subject, including the amount of time required for each visit and how long their total participation is expected to take (weeks, months, years, etc.) over the entire duration of the study.

**Ex:** Participation in this study will last approximately 30 minutes.

**Ex:** Your child will be asked to participate in 2 study visits on the UTA Campus in Arlington, Texas, and each visit will last approximately 30 minutes. The visits will be about 1 week apart.

**RESEARCH PROCEDURES**

Provide a description of all procedures involving the children in sufficient detail for a lay-person to understand. If both the parent and child will complete procedures, then they are BOTH subjects and the procedures for both parent and child will need to be described. Identify any procedures which are experimental (i.e. not validated or are currently under investigation).

**NOTE:** Per FERPA regulations, researchers must **explicitly request** the use of any FERPA-protected student educational records (such as class-assignments, grades, disciplinary records, etc) for use in a research study, regardless of whether the study will be conducted by an individual who also has legitimate educational interest in the records (i.e., a teacher). Therefore, be explicit about any assignments, grades, or other FERPA-protected student records that you would like to use for research purposes in this section of the consent!

**Ex:** If you decide to allow your child to participate in this research study, this is the list of activities that we will ask [you and] your child to perform as part of the research:

1. Read through this Informed Consent and Assent and talk with the research team to make sure that any questions you and your child may have are answered; then make your choice about whether to allow your child to participate.
2. If you agree to allow your child to participate, your child will be asked to allow a member of the research team to take his/her height, weight, and blood pressure.
3. The research team will ask you as the parent to complete a paper questionnaire about your child’s recent behavior and interactions with their friends. Please answer honestly.
4. \_\_\_\_\_\_ (Describe all procedures in a simple list fashion – add tables or other figures if needed to make the procedures clear & understandable)

**If audio/visual recordings will be used**

Include a statement explaining the recording procedures and how the recordings will be utilized for data analysis (including any potential future use). **Ex:** The interview will be audio recorded using an encrypted handheld digital recorder. After the interview, the recording will be transcribed, which means they will be typed exactly as they were recorded, word-for-word, by [a member of the research team / a professional transcription service].

**POSSIBLE BENEFITS**

Explain possible benefits to others or the contribution of knowledge to society, and describe how the research may reasonably benefit the child participant directly (i.e., receiving an exercise program that may or may not improve the child’s coordination skills; providing free tutoring to the child; etc). If the research will not benefit the participants directly, state this. **Do not list compensation of any kind (cash, course credit, gift cards) in this section.**

 **POSSIBLE RISKS/DISCOMFORTS**

Describe any foreseeable risks and/or discomforts that the child and / or his/her parent(s) may experience as a result of participating in this research study. Explain any safeguards that are in place to minimize these potential risks. If the only perceived risks and/or discomforts to participating in the study are those that participants would experience in their everyday lives, state as such.

*If participation will continue over time*, state: “any new information developed during the study that may affect your willingness to continue participation will be communicated to you.”

**Ex:** Your child might experience (list the foreseeable risks/discomforts) during this research study. (Provide an explanation of the safeguards in place to minimize the potential risks/discomforts). Remember that [you and] your child has the right to quit any study procedures at any time without penalty, and may do so by informing the research team.

**Ex:** This research study is not expected to pose any additional risks beyond what [you or] your child would normally experience in [your] or his/her regular everyday lives. However, if either of you do experience any discomfort, please inform the research team.

**COMPENSATION**

Specify the type and amount of compensation offered for participation, if any (including extra credit and non-financial payments), and explain when and how subjects can expect to receive it. Clearly explain which payments are provided to the child versus the parent; to ensure that parents do not force their children to participate for monetary compensation, it is encouraged to provide non-monetary items for the children like toys or books. If compensation is affected by withdrawal from the study, specify as such, **Ex**: If you or your child choose not to complete all study procedures, you will still receive (compensation type/amount). If no compensation will be offered for participation in this study, state this.

Also, per UTA Accounting Services policy, please add the statement below to all consent forms with payments of monetary value (cash, gift cards, iPads, etc):

“The Internal Revenue Service (IRS) considers all payments made to research subjects to be taxable income. Your personal information, including your name, address, and social security number, may be acquired from you and provided to UTA’s accounting office for the purpose of payment.  If your total payments for the year exceed $600.00, UTA will report this information to the IRS as income and you will receive a Form 1099 at the end of the year. If you receive less than $600.00 total for payments in a year, you are personally responsible for reporting the payments to the IRS.”

**ALTERNATIVE OPTIONS**

Explain any alternative procedures or courses of action that will be offered or that the child or parent(s) might find beneficial or advantageous. If there are no alternative procedures offered for this study, state as such.

**Ex:** Your child has the option to participate in other research studies or to attend physical therapy in order to find ways to develop his/her motor and coordination skills.

**Ex:** Your child has the option to participate in other research studies or complete alternative class assignments in order to fulfill his/her class requirements.

**Ex:** There are no alternative options offered for this study.

**CONFIDENTIALITY**

The research team is committed to protecting [your and] your child’s rights and privacy as a research subject. All paper and electronic data collected from this study will be stored in a secure location on the UTA campus and/or a secure UTA server for at least three (3) years after the end of this research. [If audio/visual recordings will be used, describe the storage and disposition; **Ex:** “The recording will be immediately destroyed after transcription.” OR “The recordings will be kept with the other electronic data in a secure UTA sanctioned storage device for the duration of the study.”]

The results of this study may be published and/or presented without naming [you or] your child as a participant. The data collected about [you and] your child for this study [choose one: may, will] be used for future research studies that are not described in this consent form. If that occurs, an IRB would first evaluate the use of any information that is identifiable, and confidentiality protection would be maintained. [If you know that you intend to share identifiable data with individuals outside the UTA research team or use identifiable data for future studies, you must explain how it will be used or with whom the data will be shared.]

While absolute confidentiality cannot be guaranteed, the research team will make every effort to protect the confidentiality of [your and] your child’s records as described here and to the extent permitted by law. In addition to the research team, the following entities may have access to the records, but only on a need-to-know basis: the U.S. Department of Health and Human Services and the FDA (federal regulating agencies), the reviewing IRB, and sponsors of the study.

**CONTACT FOR QUESTIONS**

Questions about this research study or reports regarding an injury or other problem may be directed to [PI/Faculty Advisor name and contact information]. Any questions you may have about [your or] your child’s rights as a research subject or complaints about the research may be directed to the Office of Research Administration; Regulatory Services at 817-272-3723 or regulatoryservices@uta.edu.

**CONSENT**

By signing this form, you are confirming that you understand the study’s purpose, procedures, potential risks, and [your and] your child’s rights as a research subject. By agreeing to [your and] your child’s participation, you are not waiving any legal rights. You and/or your child can refuse to participate or discontinue participation at any time, with no penalty or loss of benefits that you both would ordinarily have. Please sign below if you are at least 18 years of age and voluntarily agree to [participate, and] allow your child to participate in this study.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**SIGNATURE OF VOLUNTEER                                                             DATE**

*\*If you agree to participation, please provide the signed copy of this consent form to the research team. They will provide you with a copy to keep for your records.*

See next page for child assent document. The consent and assent documents may be separated if desired, but for research studies involving minor children, at least one parent must provide consent, and children who are cognitively able to provide assent must also be provided with an assent process.

If you intend to enroll children of varying ages in your study, it is encouraged to create more than one assent process to better tailor the assent to the comprehension level of children of multiple ages.

NOTE: Add at least one “assent” section for the children. Please choose the version(s) that fit(s) the age range of the children in your study. Allow ample time for the child to ask any questions.

**REMINDER: Delete all red text BEFORE IRB submission.**

**Age Range 13 - 17:
ASSENT FOR CHILD PARTICIPANT – Ages 13 – 17**

Children in this age range typically can assent by reading through the consent form provided to their parent:

By agreeing to participate, you confirm that you have read or had this entire document read to you, including the section with the consent information for your parents. You know that you can ask questions or decide not to participate at any time. No one will be upset, even if you change your mind later on.

Describe how you will obtain their assent. You may collect the child’s signature for assent, or you may accept their assent by their verbal or electronic agreement to proceed. Please see the following examples:

**Ex:** You indicate your voluntary agreement to participate by completing and returning this survey.

**Ex:** You indicate your voluntary agreement to participate by beginning this phone interview.

**Ex:** By clicking on the button below, you indicate your voluntary agreement to participate in this online survey.

**Ex:** Your signature below means that you voluntarily agree to participate in this research study.

**AGE RANGE 12 and Under:**For children under 12 years of age, it is recommended that you create a simplified version of the parental consent, and allow the child to read it on their own. You may need to verbally explain certain sections in more detail to ensure the child’s understanding, especially for children under 7 years old.

**ASSENT FOR CHILD PARTICIPANT – Ages 12 and under**

My name is [identify yourself to the child by name].

I am doing a research study, and I would like to ask you to be in my study. Research studies help us learn new things and test new ideas. This paper will tell you about our research. You can ask us questions any time.

We are asking you to take part in a research study because we are trying to learn more about [outline what the study is about in a language that is both appropriate to the child’s maturity, age, and reading level]. It is your choice whether or not you want to take part in this research study. I will tell you more about the study so that you can decide.

If you say yes to be in this study, [describe the experience of completing the research procedures and data collection from the child’s point of view].

[Describe any risks to the child that may result from participation in the research, including any discomfort or distress that may be caused.]

[Describe any direct benefits to the child that may result from participation in the research.]

Please talk with your Mom or Dad [or Guardian] about your choice before you make your decision. We will also ask them if it is okay for you to be in this study. But even if they say “yes,” you can still decide not to do this at any time.

If you don’t want to be in this study, you do not have to. Remember, being in this study is up to you and no one will be mad or upset, even if you change your mind later and want to stop before you are finished. That is okay.

You can ask me any questions that you have about the study now. If you have a question later that that you didn’t think of now, you or your parents can call or email me, or you can ask me when I see you next time.

Describe how you will obtain their assent. You may obtain assent through their verbal response, a signature, or their agreement to proceed.

**Ex.** Verbally ask the child: Would you like to be in this research study? If you say “yes,” then you agree to be in this study.

**Note:** For very young children or infants with limited capability that cannot reasonably be consulted, an assent process may not be appropriate. In this case, the child assent process can be waived, and permission would be obtained solely from the parent(s).