# Delete all instructions in blue before submitting to the IRB

**Use this template when the parent gives permission and the child gives separate assent.**

Instructions are in blue. Customize the language in black as needed to fit your study. When you have finished, ***read over*** the entire document to ensure it makes sense and is accurate.

* Use simple language. Avoid technical terms.
* Write in a conversational tone, as though you’re speaking to your participants.
* Use pronouns (I, we, you) and contractions (we’re, won’t, isn’t). The template default is “we”; you can change this to “I” if you’re doing the research entirely on your own.
* Use short paragraphs (~4 lines or less). Don’t write walls of text.
* Feel free to use bullet points, tables, graphs, pictures, diagrams, etc. to more clearly convey the study information.

Study title: [insert]

## Summary Statement: [include activities, risks and benefits]

**[Use if research is federally funded] Funding source:** [insert funding source] is funding this research study.

Researcher[s]**:** [insert name(s) and title / degree / department, as applicable]

We’re inviting you to participate in a research study. Participation is completely voluntary. If you agree to participate, you can always change your mind and withdraw. There are no negative consequences, whatever you decide.

## What is the purpose of this study?

[describe the purpose or goals in simple language]

**Examples:** We want to understand how young children learn to pronounce certain sounds. **– or –** We want to study whether giving children information about healthy eating helps them make better choices in the lunch room.

## What will my child do?

[Describe all study procedures in simple language, and include the amount of time each activity will take. For multiple procedures, use separate paragraphs or bullet points for each to make it easy to read.

If your study includes surveys or interviews, briefly describe the types of questions that will be asked. If there are any questions that parents or children could find objectionable, be sure to indicate that here as well.]

**Examples:** Your child will be in a focus group with about 5 other children, ages 10-13. A focus group is a discussion with a group of people about a certain topic. They will discuss and share their experiences helping care for an adult with a disability, and ways that doctors and others could provide them more support.

 **– or –**

* In our lab:
	+ We’ll ask your child questions about their health and exercise habits. (10 minutes)
	+ We’ll measure height and weight. (5 minutes)
	+ We’ll teach your child some exercises, and they’ll rate how easy and fun the exercises are. (30 minutes)
* At home afterward:
	+ We’ll ask your child to do each exercise for 5 minutes per day.
	+ Your child will keep a daily diary for 2 weeks to keep track of how often they do these exercises, and give feedback about the exercises.
	+ At the end of 2 weeks, you’ll mail the diary back to us in the envelope we provide.

How long will it take?,[insert total amount of time for individual participation]

Recordings / Photographs[Delete this row if n/a]**,** We will record / photograph your child. The recordings / photographs will be used for [explain].

* The recording / photography is optional. **– or –** The recording / photography is necessary to this research. If you do not want your child to be recorded / photographed, they should not be in this study.

Estimated number of participants **-** [insert #. If needed, add explanation or description of different groups, e.g. 40 teachers and 300 students]

Costs **-** [Describe. **Examples:** None **– or –** You’ll pay for your own transportation and parking]

Compensation **-** [Describe. **Examples:** None **– or –** $10 Amazon gift card] [describe how the payment will be made (e.g. cash, gift card), whether it will be issued all at once or in increments. Include when the payment will be issued, beginning or end of participation. Also add whether a participant has to participant in the entire study OR if they withdraw early they will not receive the incentive or will receive a prorated rate.]

If I don’t want my child to be in this study, are there other options? [If the only alternative is not to participate, delete this row.]Instead of participating, your child can [insert alternative(s)] **Example:** Instead of participating, your child can receive individual therapy through our office. We can provide details if you’re interested in learning more.

## Risks - Possible risks and how we’re minimizing these risks

Some questions may be very personal or upsetting [Delete this row if n/a]. Your child can skip any questions they don’t want to answer.

Others in the focus group sharing your child’s responses [Delete this row if not a focus group]. We ask all participants to keep everything said during the focus group confidential. However, we can’t control what others say, so we also remind everyone not to share anything they don’t want others to know.

Breach of confidentiality (your child’s data being seen by someone who shouldn’t have access to it). [Use whichever of the following bullet points apply to your study. Add any other measures you’ll use to protect data security.]

* Data is anonymous. **– or –** All identifying information is removed and replaced with a study ID.
* We’ll remove all identifiers after [insert amount of time or specific event].
* We’ll store all electronic data on a password-protected, encrypted computer.
* We’ll store all paper data in a locked filing cabinet in a locked office.
* We’ll keep your child’s identifying information separate from the research data, but we’ll be able to link it to them by using a study ID. We will destroy this link after we finish collecting and analyzing the data.
* Online data being hacked or intercepted [delete this row if not an online survey], This is a risk everyone experiences any time they provide information online. We’re using a secure system to collect this data [elaborate if desired], but we can’t completely eliminate this risk.
* Radiation exposure [delete this row if n/a], **Example:** When your child has the bone density test (DXA scan), they’ll be exposed to a small amount of radiation. The overall effect of radiation on the human body is measured in terms of Roentgen equivalents in man, or "rem". They’ll be exposed to a total of approximately 0.00012 rem for all the scans. In comparison, the amount of radiation received during a routine chest x-ray is 0.01 rem. The risk of harm from radiation exposure of this amount is too small to estimate.

Add more rows for any other risks – think about physical, emotional, social, and/or financial risks.,

There may be risks we don’t know about yet. Throughout the study, we’ll tell you if we learn anything that might affect your decision to let your child participate.

**[Use if more than minimal risk. Edit as applicable to the specific potential risks in your research]** What if my child is harmed from being in this study?

If your child is harmed from being in this study, let us know. If it’s an emergency, get help from 911 or your child’s doctor right away and tell us afterward. We can help you find resources if your child needs psychological help. You or your insurance will have to pay for all costs of any treatment.

Possible benefits -[List individual benefits (if any).] [List benefits to a larger group or society (such as helping understand more about xyz).] **[Don’t** include compensation here; you’ll describe that below.]

## Confidentiality and Data Security

If applicable: Add “biospecimens”, or substitute “biospecimens” for “data” throughout this section.

[Include if applicable] We’ll collect the following identifying information for the research: [list. **Examples:** your child’s name and birth date]. This information is necessary [explain why / what it will be used for. **Example:** This information is necessary so that we can compile all your child’s data, and compare children by age when we analyze the data].

Where will data be stored? **-** [Explain] **Examples:** On our computers **– or –** In my office at UWM

**How long will it be kept?** - [insert amount of time]

## Who can see my child’s data?

* We (the researchers) will have access to [insert type of data; **Examples:** identifiable (with your name included) **– or –** coded (names removed and labeled with a study ID) **– or –** de-identified (no names, birthdate, address, etc.)]. This is so we can analyze the data and conduct the study.
* The Institutional Review Board (IRB) at UML, the Office for Human Research Protections (OHRP), or other federal agencies may review all the study data. This is to ensure we’re following laws and ethical guidelines.
* We may share our findings in publications or presentations. If we do, the results will be [state the kind of data that will be included in dissemination of your work. **Examples:** aggregate (grouped) data, with no individual results **– or –** de-identified (no names, birthdate, address, etc.).] If we quote you, we’ll use pseudonyms (fake names).
* [Delete if n/a] Our funding agency requires us to make our dataset public so other researchers can use it. This public dataset will include only [state the kind of data that will be included. **Examples:** aggregate (grouped) data, with no individual results. **– or –** de-identified (no names, birthdate, address, etc.).
* [Delete if n/a] Amazon: Because they own the MTurk internal software, and to issue payment, Amazon will have access to your MTurk worker ID. There is a possibility Amazon could link your worker ID (and associated personal information) with your survey responses.
* Add anyone else who may potentially access the data. Describe the purpose of this disclosure, and what type of data (identifiable, de-identified, etc.).

## Other Study Information

**Future research,** De-identified (all identifying information removed) data / biospecimens may be shared with other researchers. You won’t be told specific details about these future research studies. **– or –** Your child’s data / biospecimens won’t be used or shared for any future research studies.

If your child’s biospecimens are used for commercial profits, these profits won’t be shared with you.

**Removal from the study [Delete section if N/A]** [Describe any circumstances that would result in a participant being removed from the study. **Example:** In order for our data to be useful, it is important that your child attend every mindfulness session. If your child misses a session and can’t reschedule, we’ll have to take them out of the study.]

**Gene sequencing [Delete section if N/A]** The specimens your child provides will be used in genetic research. This research may include whole genome sequencing. [explain specifically what genetic research will be done in clear, easy to understand language.]

**[Use if a clinical trial, delete if N/A]** A description of this study will be posted on [U.S. National Library of Medicne website](https://clinicaltrials.gov/) You can search this website at any time. This website won’t include information that can identify your child. At most, it will include a summary of the results.

**[Use if child abuse may be discovered during the research, delete section if N/A] Mandated Reporting**

We are mandated reporters. This means that if we learn or suspect that a child is being abused or neglected, we’re required to report this to the authorities.

**[Use if NIH funded, delete section if N/A] This study has a Certificate of Confidentiality**

To help us protect your child’s privacy, we have a Certificate of Confidentiality from the National Institutes of Health (NIH). With this certificate, we can’t be forced by a court order or subpoena to disclose information that could identify your child.

There are times when your child’s identity wouldn’t be kept secret, even with this certificate:

* If a government agency inspects the records, or to meet FDA requirements
* If you give someone written permission to receive this information, or if you tell someone the information yourself
* If your child threatens to harm him-/herself or others
* In cases of child abuse
* If we’re required to report cases of certain contagious diseases (such as HIV) to the state

## Contact information:

**For questions about the research, complaints, or problems:** Contact [insert Researcher name(s), phone & email, or other best contact method].

**For questions about your rights as a research participant, complaints, or problems:** Contact the UMass LowellIRB (Institutional Review Board) at 978-934-4134 or at IRB@uml.edu

## Signatures

If you have had all your questions answered and give permission for your child to participate in this study, sign on the lines below. Remember, your child’s participation is completely voluntary, and you’re free to remove them from the study at any time.

Name of Child (print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Parent or Guardian (print):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Parent or Guardian: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**[Use if the researcher will obtain informed consent in person]**

Name of Researcher obtaining consent (print):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Researcher obtaining consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_