# **DELETE ALL INSTRUCTIONS IN BLUE BEFORE SUBMITTING TO THE IRB**

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.
* For sections that are not applicable, delete the section.

**For studies deemed Expedited or Committee review the consent must have a Key Information section and a Study Details section**. The initial summary should **not exceed three** pages.

The Key Information section should include a summary of the main information that research participants need to know to make a decision about whether they would want to participate in the study or not (what a reasonable person would want to know). It should be concise, focused, and use lay language. Organize this summary in a way that helps research participants understand what they are being asked to consider. The key information and study details should be integrated in a way that limits redundancy and helps research participants ask questions and make a decision.

Defer the specific details of the study until the Study Details section of the consent.

**Study title:** [insert]

**Funding source:** [if applicable, insert funding source. If there is no funding delete] is funding this research study.

**Researcher[s]:** [insert name(s) / professional credentials / department, as applicable]

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

**Key Information**

**Your child is being invited to participate in a research study** because [state reason why they are being asked to participate].

If you have questions or don’t understand something, please ask.

Taking part in this research is voluntary and completely up to you. You are free to say no or to leave the research at any time. There will be no penalties and you will not lose any benefits to which you are otherwise entitled.

**The main question this study is trying to answer** is [indicate the main purpose(s) of the study in very simple language].

**If your child joins this research,** they will be asked to do the following:

* A
* B

**You may not want your child to be in this study if you or your child are uncomfortable with:**

* Answering questions about…
* Sharing your private information with researchers

**Risks:** Do not include the complete list of reasonably foreseeable risks from the study details section of the consent form. This section should identify only the most important risks.

We will take steps to protect your child’s personal information. However, there is a risk of breach of confidentiality.

There may also be risks that we do not know yet.

**Benefits:** Describe any potential benefits to others. Your child’s participation will help us to gain knowledge that may help treat X in the future.

* If there are possible benefits to the participant:

We cannot promise any benefits to your child if they take part in this research. Your child may benefit from Describe any potential direct benefits to the participant. If benefits from taking part may not continue after this research has ended, describe this. Avoid stating that being in the study and being monitored is a direct benefit.

* If there are no expected benefits to the participant but possible benefits to others/scientific knowledge:

However, there is no direct benefit to your child.

**Alternatives:** Clearly state here if there are alternatives to participating in the research.

If there are no alternatives, state: The alternative is to not take part in the research.

**Conflict of Interest:** Insert any conflict of interest disclosures or remove this section if there is nothing to disclose

**If you think you might like your child to participate in this research, please continue reading to learn more about the details of this study.**

**STUDY DETAILS**

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

[describe the purpose or goals in simple language]

## **What will my child do and how long will it take?**

[Describe the survey topic(s) and the types of questions that will be asked. If there are any questions that participants could find objectionable, be sure to indicate that here as well. Insert total amount of time for individual participation.

Recordings / Photographs [Delete this row if n/a] We will audio and/or video 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, you should not allow them to be in this study.

**Could being in this research hurt my child?**

* [Breach of confidentiality] There is a chance your child’s data could be seen by someone who shouldn’t have access to it. We’re minimizing this risk in the following ways: [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 store all electronic data on the UML server or UML OneDrive **– or –** On the servers for the online survey software (Qualtrics).
	+ We’ll keep your child’s identifying information separate from their research data, but we will be able to link it to them via a Key Code. We’ll destroy this link after we finish collecting and analyzing the data.
* [use for studies that ask participants to provide **sensitive** information] Some questions may be personal or upsetting. Your child can skip any questions they don’t want to answer, or stop the research at any time.
* [use for Online surveys/questionnaires] There is a risk that your online data could be intercepted: This is a risk you experience any time you provide information online. We’re using a secure system to collect this data, but we can’t completely eliminate this risk.
* [use for Focus Groups] Researchers cannot guarantee that your child’s responses will remain confidential after the session has ended.
* [For studies with venipuncture] The risks of having blood drawn include slight pain when the needle is inserted. Your child may develop a harmless black and blue mark, and their arm may be sore. Infection, light-headedness, and fainting are also possible, but unlikely.
* [For studies with ECG] The risks include skin irritation and a rash from wearing or removing the patches that stick to your child’s skin or from the gel that is used with them.
* Add any other risks – think about emotional, social, and/or financial risks.
* [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 l 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.

**What happens if my child is injured because they took part in this research?**

[This section is required for all non-exempt research.]

Your child’s welfare is a concern of every member of the research team. If they have a problem as a direct result of being in this study, you should immediately contact one of the people listed at the beginning of this consent form and seek medical attention. The University of Massachusetts Lowell does not provide funds for the treatment of research-related injury. If your child is injured as a result of their participation in this study, you or your child’s insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available. You do not give up any of your legal rights by signing this form.

## **What other choices do I have besides allowing my child to participate in this research?**

**If there is an alternative state:** Instead of participating, your child can [insert alternative(s)] **Example:** Instead of participating, you can earn the same amount of extra credit by answering questions 1-2 on page 394 of your textbook.

**If there are no alternatives, state:** Your alternative is to not to allow your child to participate in the research.

**Will being in this research help my child in any way?** List individual benefits (if any). **Don’t include compensation here; that will be described below**.

**Will it cost me any money to allow my child to participate in this research?** None **– or –** describe any costs to participants

**Will my child receive an incentive for participating in this study?** [describe how the payment will be made (e.g. 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 participate in the entire study OR if they withdraw early whether they will not receive the incentive OR will receive a prorated rate.]

**Can my child be removed from the research without my approval? [Delete this 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 you attend every mindfulness session. If you miss a session and can’t reschedule, we’ll have to take you out of the study.]

## **How will my child’s information [and specimens] be stored and when will [it/they] be destroyed?**

[Describe how data and specimens will be stored such that they are kept confidential. Indicate when they will be destroyed. For example: We will remove your name and any other information that could directly identify you from your data [and specimens]. We will replace this information with a code number. We will create a master list linking your code number to your name. We will keep this list separate from your data [and specimens].

**[Choose one** of the following or use the sponsor’s comparable language:]

We will not use or share your child’s data [and specimens] for any future research unrelated to this study, even if identifiers are removed.

It is possible that we might use the research data [and specimens] in other future research. We may also share data [and specimens] with researchers and companies that are not part of UML. In these cases, we will not share your child’s name or other information that identifies them directly, and we will not come back to you to ask you for your consent.

**[Use if Gene sequencing [Delete this section if not using biospecimens]** 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.

– or –

Your child’s specimens will not be used for any genetic research or gene sequencing.

**[Delete this section if no biospecimens, or if no commercial profits are expected to result from the research]. Financial profits from research** If the researcher / sponsor earns financial profits from using your biospecimens in this research, these profits will / won’t be shared with you.

**[Use if a clinical trial]** A description of this study will be posted on [U.S National Library of Medicine 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.

## **Who can see my data?**

* We (the researchers) will have access to all data. This is so we can analyze the data and conduct the study.
* The Institutional Review Board (IRB) at UML [or insert federal funder] 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.).
* **[If conducting research with minors: If child abuse is discovered during the research add the following]** 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.
* Add anyone else who may potentially access the data. Describe the purpose of this disclosure, and what type of data (identifiable, de-identified, etc.).

**[Use if NIH funded] Does this study have a Certificate of Confidentiality?**

Because the National Institutes of Health (NIH) funds this research, this study has a Certificate of Confidentiality. The Certificate keeps us from sharing your child’s identifiable sensitive information collected for the research unless you allow us to do so. It also keeps us from being forced to release information that may identify your child, as part of a court, legislative, administrative, or other proceeding.

Identifiable sensitive information includes specimens gathered during the research if there is a small risk of being able to identify you from those specimens, if they are combined with other information.

There are times when the Certificate cannot be used. For example, we cannot refuse to give information to government agencies that oversee or fund research, such as the NIH or Food and Drug Administration (FDA). The Certificate also does not stop us from giving information to local government agencies, law enforcement personnel, or others if we suspect you or someone else is in danger or if we are required to do so by law.

The Certificate does not stop you from giving out information about your child or their participation in the research. If you give an insurer, employer, or someone else your permission for us to release information, we will do so.

## **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 child’s rights as a research participant, complaints, or problems:** Contact the UMass LowellIRB (Institutional Review Board) at 978-934-4134 or at IRB@uml.edu

**Signature Block for Parents/Guardian**

Your signature documents your consent for your child to participate in this research.

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| Signature of parent/guardian |  | Date |
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| Printed name of parent/guardian |  |  |
|  |  |  |
| Printed name of your child |  |  |
| Signature of person obtaining consent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  |  |