# Delete all instructions in blue before submitting to the IRB

**This template can be used for studies where the activities involve but are not limited to, surveys/questionnaires, interviews, and focus groups. If you are doing an online survey, make this consent document the first question/page of your survey.**

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.

Study title**:** [insert]

Summary Statement**:** [include activities, risks and benefits – a summary statement is required for studies that are approved under the Expedited/Full procedures. The summary should not exceed a paragraph, i.e., 5 sentences.]

**[Use if research is federally funded, if not Delete section] Funding source:** [insert funding source] is funding this research study.

Researcher[s**]:** [insert name(s) / professional credentials / 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]

## What will I 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 record / photograph you. 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 to be recorded / photographed, you should not be in this study.

Risks **[customize as needed to fit your study]**

* Some questions may be very personal or upsetting. You can skip any questions you 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 hacked or intercepted: This is a risk you experience any time you provide information online. We’re using a secure system to collect this data [elaborate if desired], but we can’t completely eliminate this risk.
* [use for MTurk surveys] Amazon could link your worker ID (and associated personal information) with your survey responses, if you use an internal HIT. Make sure you have read Amazon’s MTurk participant and privacy agreements to understand how your personal information may be used or disclosed.
* [use for focus groups] Since researchers cannot guarantee that your responses will remain confidential after the session has ended, therefore it is advised that you consider whether you want to risk disclosing any particularly sensitive information.
* Breach of confidentiality: There is a chance your 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 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 keep your identifying information separate from your research data, but we will be able to link it to you. We’ll destroy this link after we finish collecting and analyzing the data.
* Add any other risks – think about emotional, social, and/or financial risks.
* [Radiation exposure [delete this row if n/a] Example: When you have the bone density test (DXA scan), you’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". You’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.

Possible benefits: List individual benefits (if any). **Don’t include compensation here; that will be described below**.

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

Costs: None **– or –** describe any costs to participants

Compensation: [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 the only alternative is not to participate, delete this paragraph.]** **If I don’t want to be in this study, are there other options?** Instead of participating, you 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.

Removal from the study **[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.]

Future research[Delete this section if “N/A”]**:** De-identified data (all identifying information removed) may be shared with other researchers. You won’t be told specific details about these future research studies. **– or –** Your data won’t be used or shared for any future research studies.

## Confidentiality and Data Security:

[Include if applicable] We’ll collect the following identifying information for the research: [list. **Examples:** your name, email address, and the psychology class you’re enrolled in]. This information is necessary [explain why / what it will be used for. **Example:** This information is necessary so that you can receive extra credit] [For information on data security, please visit the UML IRB IT security policy [HERE](https://www.uml.edu/docs/IRB%20Data%20Security%20Policy_IT-5-113_09.29.16_tcm18-288469.pdf)].

Where will data be stored and how long will it be kept? [Explain] **Example:** On the researchers’ encrypted, password protected computers, on the UML server **– or –** On the servers for the online survey software (Qualtrics). Insert amount of time the data will be kept and when it will be destroyed]

## Who can see my 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.).

**[Use if Gene sequencing [Delete this section if not using biospecimens]** The specimens you provide 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 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 you. At most, it will include a summary of the results.

**[Use if child abuse may be discovered during the research] 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] This study has a Certificate of Confidentiality**

To help us protect your 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 you.

There are times when your 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 you threaten to harm yourself or others
* In cases of child abuse
* If we’re required to report cases of certain contagious diseases (such as HIV) to the state

**[Use if any researchers have a conflict of interest] Conflict of Interest**

[List the name and a brief description of any potential conflict of interest. Include how the conflict is being managed, in accordance with the approved management plan.]

## 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

**Agreement to Participate [If you will be collecting signed consent forms]**

I confirm I am volunteering freely to participate in this research project. I have read and fully understand the purpose of the research project and its risks and benefits. I have had the opportunity to read this document and discuss my concerns and questions. I consent to participate in this research.

Printed Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature:

## RESEARCHER/PERSON OBTAINING CONSENT

*I have provided a copy of this document and reviewed with the participant the materials contained in this form and the participant has provided consent to participate.*

Printed Name of Researcher: ­­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature:

If you will be obtaining **ELECTRONIC CONSENT use the following:**

Please select your choice below. You may print a copy of this consent form for your records. Clicking on the “Agree” button indicates that

* You have read and understand the above information
* You voluntarily agree to participate in the research
* You are 18 years of age or older

🞎 Agree

🞎 Disagree