# 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 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.]

**[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.

Could being in this research hurt me?

* [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 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 identifying information separate from your research data, but we will be able to link it to you 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. 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 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, it is advised that you consider whether you want to risk disclosing any particularly sensitive information.
* [For studies with venipuncture] The risks of having blood drawn include slight pain when the needle is inserted. You may develop a harmless black and blue mark, and your 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 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 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.

What happens if I am injured because I took part in this research?

If the study is not funded or being supported by a federal grant, or institutional funding mechanism, please use the following language. This section is required for all non-exempt research.

Your welfare is a concern of every member of the research team. If you 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. The University of Massachusetts Lowell does not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, you or your 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.

Use the following language for industry sponsored research. This language is consistent with the clinical trial agreement for all studies that are greater than minimal risk.

If you are injured while in the study, seek treatment and contact the study doctor as soon as you are able.

If you are injured or have any harmful effects as a direct result of the administration of X (e.g. study drug or device) or any procedure required by the research, necessary medical treatment will be made available to you. The sponsor, X, will pay the reasonable and necessary medical costs for study-related injury.

To pay these medical expenses for a research injury, the sponsor will need certain information about you, such as your name, date of birth, and social security number. This is because the sponsor has to check to see if you receive Medicare. If you do, the sponsor must report the payment it makes to Medicare. The sponsor cannot use your information for any other purpose.

The sponsor has no plans to pay for medical expenses for injuries that are not directly related to your research participation or that are caused by the natural course of your disease. The sponsor has no funds set aside for any other form of compensation in the event of a research injury.

You do not give up any of your legal rights by signing this form.

## What other choices do I have besides taking part in this research?

**If there is an alternative state:** 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.

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

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

How many people will take part in this research? [insert #. If needed, add explanation or description of different groups, e.g. 40 teachers and 300 students]

Will it cost me any money to take part in this research? None **– or –** describe any costs to participants

Will I receive any compensation or 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 participant in the entire study OR if they withdraw early whether they will not receive the incentive or will receive a prorated rate.]

If collecting names to issue an incentive add the following: In order to receive a stipend for study participation, you may need to give us private information like your name. We may then share this information with the UML Controller’s Office that require this information to process the payment. NOTE: You will need to provide your social security number and complete a W-9 (tax form) if you receive:

* $600 or more in a calendar year across multiple research studies at UML.

UML may report the payment to the IRS and send you a 1099 form for tax purposes. The business offices and companies will keep the information as part of their financial records. The research team will destroy this information three years after study closure.

Can I 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 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 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 name or other information that identifies you 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 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.

## 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 [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.).
* [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.
* **[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 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 you, 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 yourself or your participation in the research. If you give an insurer, employer, or someone else your permission for us to release information, we will do so.

**[Use if any researchers have a conflict of interest] Do any of the researchers have a 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](mailto:IRB@uml.edu)

**Use Signature Block below if obtaining DOCUMENTATION (WRITTEN) CONSENT:**

**Signature Block for Capable Adults**

Your signature documents your consent to take part in this research.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of adult research participant |  | Date |
|  |  |  |
| Printed name of adult research participant |  |  |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  |  |

**Use acknowledgment section below if obtaining ELECTRONIC CONSENT:**

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

**Use the following for obtaining VERBAL CONSENT:**

Before we begin,

1. Are you 18 years of age or older? \_\_\_Yes or \_\_\_No If no, thank you for your time!
2. Do you have any questions? \_\_\_Yes or \_\_\_No
3. Do you agree to voluntarily participate in this research? \_\_\_Yes or \_\_\_No (STOP HERE)
4. If applicable, do you agree to be audio and/or video recorded? \_\_\_Yes or \_\_\_No

**Researcher Obtaining Verbal Consent:**

Name of Researcher:

Date of Verbal Consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Time:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Obtained Verbal consent via:  in-person  phone  Zoom/video conference

Use Signature Block below for ADULTS UNABLE TO CONSENT AND CAPABLE ADULTS

Signature block for studies that may or will involve adults unable to consent and may also include adults that have capacity to consent

Right click your mouse to delete or adjust table rows

Add one of the following:

* All research participants unable to consent are required to assent, unless the investigator determines that the capability of the individual is so limited that they cannot reasonably be consulted.
* All research participants unable to consent are required to assent.
* The assent of adult research participants unable to consent is not required.

If assent will be obtained, add one of the following:

* If assent is obtained, have the person obtaining assent document assent on the consent form.
* If assent is obtained, have the research participant sign the consent form, unless the investigator determines that the individual is not capable of signing.
* Documentation of assent is not required.

Always add:

|  |  |  |
| --- | --- | --- |
| Your signature documents your permission for you or the individual named below to take part in this research. | | |
|  |  |  |
| Signature of adult capable of consent or adult’s legally authorized representative |  | Date |
|  |  |  |
| Printed name of research participant or their legally authorized representative |  | Date |
|  |  |  |
| Explain representative’s relationship to, and authority to act on behalf of, the research participant |  |  |
|  | | |
| Printed name of research participant if they did not personally sign |  |  |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  |  |

If the person obtaining assent will document assent on the consent form, add:

|  |  |  |
| --- | --- | --- |
| * I have explained the study to the extent compatible with the research participant’s capability, and they have agreed to be in the study.   OR   * The research participant is not able to assent because their capability is so limited that they cannot reasonably be consulted. | | |
|  |  |  |
| Signature of person obtaining assent |  | Date |

If documentation of assent is by having the participant sign the consent form, add:

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of research participant |  | Date |

**Signature Block for Witness**

Add on an as needed basis to the last page if a witness will observe the consent process. Be sure that the study plan describes when a witness will be use, e.g., with the short form of consent documentation and an interpreter, or research participants who are unable to read or physically unable to sign. Do not add to every consent document unless every research participant will have a witness to the consent process.

|  |  |  |
| --- | --- | --- |
| My signature below documents that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the research participant, and that consent was freely given by the research participant. | | |
|  |  |  |
| Signature of witness to consent process |  | Date |