***Delete all instructions in red before submitting to the IRB***

Instructions are in red. 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] |
| **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 now, you can always change your mind later. There are no negative consequences, whatever you decide.

If the consent document (excluding signature lines) is more than 4 pages, it must begin with a concise and focused presentation of key information that will help a subject decide whether or not to participate. Complete this box with a very brief explanation in simple language for each line below. You can provide more details later in the document.

For consent documents 4 pages or less, delete this box.

**Overview**

**Purpose:**

**Procedures:**

**Time Commitment:**

**Primary risks:**

**Benefits:** (NOT compensation)

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

[describe the purpose or goals in simple language]

**Examples:** We want to understand whether music helps the brain work better. **– or –** We want to study whether using an app to track what you eat helps you make healthier choices.

**What will I do?**

[Describe all study procedures in simple language. For studies with multiple activities, include the amount of time each activity will take, and use separate paragraphs or bullet points 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 participants could find objectionable, be sure to indicate that here as well.]

**Examples:** You’ll be in a focus group with about 5 other people. A focus group is a discussion with a group of people about a certain topic. You’ll discuss and share your experiences raising a child with autism, and ways that doctors and others could provide you more support.

**– or –**

* In our lab:
  + You’ll complete a survey about your health history and how often you exercise. (10 minutes)
  + We’ll measure your height and weight. (5 minutes)
  + We’ll teach you some exercises, and you’ll rate how easy and fun you think they would be to do. (45 minutes)
* At home afterward:
  + We’ll ask you to do each exercise for 5 minutes per day.
  + You’ll keep a daily diary for 2 weeks to keep track of how often you 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.

**– or –** I will ask you questions about your marriage, how you divide chores, and things you and your spouse enjoy doing together. The interview will include questions about your sex life and whether you have ever cheated on your spouse. The total time will be about 30-45 minutes.

**Risks**

|  |  |
| --- | --- |
| **Possible risks** | **How we’re minimizing these risks** |
| Some questions may be personal or upsetting [Delete this row if n/a] | You can skip any questions you don’t want to answer. |
| Others in the focus group could share your responses [Delete this row if not a focus group] | We ask everyone to keep everything said during the focus group confidential. However, we can’t control what others say, so it is best not to share anything you don’t want others to know. |
| Breach of confidentiality (your 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 identifying information separate from your research data, but we’ll be able to link it to you 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 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. |
| Amazon could link your worker ID and personal information with your survey responses. [delete this row if not an MTurk survey] | * Make sure you have read Amazon’s MTurk participant and privacy agreements to understand how your personal information may be used or disclosed. |
| 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. |
| 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 participate.

**Other Study Information**

|  |  |
| --- | --- |
| **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.] |
| **Estimated number of participants** | [insert #. If needed, add explanation or description of different groups, e.g. 40 teachers and 300 students] |
| **How long will it take?** | [insert the total time commitment for the participant] |
| **Costs** | [Describe. **Examples:** None **– or –** You’ll pay for your own transportation and parking] |
| **Compensation** | [Describe. **Examples:** None **– or –** $10 Amazon gift card **– or –** 1 hour extra credit]  [Use the following if participants are paid through UWM accounts payable, and you have NOT requested level 3 confidentiality]Due to UWM policy and IRS regulations, we may have to collect your name, address, social security / tax ID number, and signature to give you this compensation. |
| **If I don’t want to be in this study, are there other options?** [If the only alternative is not to participate, delete this row.] | 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. |
| **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 data / biospecimens won’t be used or shared for any future research studies. |
| **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. |
| **Removal from the study** [Delete this row 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.] |
| **Gene sequencing** [Delete this row 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. |
| **Funding source** [Delete this row if n/a] | [insert funding source] |
| **Financial profits** [Delete this row if no biospecimens, or if no commercial profits are expected to result from the 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 more than minimal risk. Edit for the specific potential risks in your research] What if I am harmed because I was in this study?**

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

**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 name and email address]. This information is necessary [explain why / what it will be used for. **Example:** This information is necessary so that you can receive extra credit].

|  |  |
| --- | --- |
| **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 data?** | **Why?** | **Type of data** |
| The researchers | To conduct the study and analyze the data | [State the kind of data you will collect/keep, with a brief explanation what that means.] **Examples:** Identifiable (with your name included) **– or –** Coded (names removed and labeled with a study ID) **– or –** De-identified (no names, birthdate, address, etc. attached to the data) |
| The IRB (Institutional Review Board) at UWM  The Office for Human Research Protections (OHRP) or other federal agencies | To ensure we’re following laws and ethical guidelines | [This should be the same as above.] |
| Anyone (public) | If we share our findings in publications or presentations  [use if applicable] Our funding agency requires us to make our dataset public so other researchers can use it. | [State the kind of data that will be included in dissemination of your work, or in public datasets.] **Examples:**   * Aggregate (grouped) data * De-identified (no names, birthdate, address, etc.) * If we quote you, we’ll use a pseudonym (fake name) |
| Amazon [delete this row if not an MTurk survey] | Because they own the MTurk internal software, and to issue payment | * MTurk worker IDs * There is a possibility Amazon could link your worker ID (and associated personal information) with your survey responses. |
| Include additional rows if there is anyone else who might access the data. Describe the purpose of this disclosure and what type of data (identifiable, de-identified, etc.). |  |  |

**[Use if a clinical trial]** A description of this study will be posted on <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 paragraph + following bullet points 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. However, there are times when your identity wouldn’t be kept secret, even with a Certificate of Confidentiality:

* 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** | [insert Researcher name(s)] | [insert phone & email, or other best contact method] |
| **For questions about your rights as a research participant** | IRB (Institutional Review Board; provides ethics oversight) | 414-229-3173 / [irbinfo@uwm.edu](mailto:irbinfo@uwm.edu) |
| **For complaints or problems** | [insert Researcher name(s)] | [insert contact information] |
| IRB | 414-229-3173 / [irbinfo@uwm.edu](mailto:irbinfo@uwm.edu) |

**Signatures**

If you have had all your questions answered and would like to participate in this study, sign on the lines below. Remember, your participation is completely voluntary, and you’re free to withdraw from the study at any time.

Name of Participant (print)

Signature of Participant Date

**[Use if minors or individuals with a Legally Authorized Representative may be enrolled] If participant is a minor or requires a Legally Authorized Representative:**

Name of Parent, Guardian or Legally Authorized Representative (print)

Signature of Parent, Guardian or Legally Authorized Representative Date

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

Name of Researcher obtaining consent (print)

Signature of Researcher obtaining consent Date