Informed Consent

[*Note to the researcher: Please use this template when creating the informed consent documents for your studies. See directions and examples (in brackets, italicized). Be sure to update these accordingly for the given study and remove as needed.*]

# Title of Research Project:

# Principal Investigator [*or Faculty Research Advisor*]:

*[prefix, name institutional affiliation/department, email address, phone number]*

# Associate Investigators [*or Student Researchers*]:

*[researcher names and email addresses]*

## **Invitation to Participate in Research:**

You are invited to participate in a research study. The purpose of this information is to help you to make an informed decision about whether or not you would like to participate. Please read the information in this document carefully. You may ask the researchers [*or contact the researchers to ask (if the study is not in-person)*] questions about the purpose of the research, what you would be asked to do, any possible risks and benefits, your rights if you were to participate, and anything else about the research before deciding whether or not to participate.

Participation in this study is voluntary and confidential. If you do not wish to participate or if you decide to participate and then withdraw or skip any part of the research process, there are no penalties or loss of benefits or services that you are otherwise entitled. Whether or not you choose to participate in this project will have no effect on your relationship with the researchers or Daemen University [*add any collaborative institution or affiliate*].

*[Note: for consent forms longer than 4 pages, this section must also include a concise and focused summary of the key information most likely to help prospective subjects understand the reasons they may or may not want to participate. This information must be organized and presented in a manner that facilitates understanding. Sample language might include the following - adjust accordingly: “The purpose of the research is to examine (brief purpose). Participants will be asked to (brief procedures), and participation is expected to take… There are no anticipated risks beyond those likely to be experienced in daily life, and there are no benefits or costs associated with participation. All data will be kept confidential.”]*

## **Purpose of the Research Project:**

The purpose of this research study is to examine…[*Describe the purpose of the study.*]

## **Description of the Research Project and Procedures:**

Participants will be asked to… [*Describe the research procedures in sufficient detail to facilitate full understanding of what participants will be asked to do. This should include step-by-step descriptions of each type of task and survey instrument (example questions are encouraged, especially if the items are sensitive in nature) that participants will encounter*.]

To be included in this study, participants should: [*Describe inclusion criteria, if any. Note: inclusion criteria are a set of criteria that indicates the qualities a participant must have in order to continue study participation, which often involves post-consent screening procedures. This does not refer to which participants’ data will be included in data analysis*.]

Things that would exclude a participant from this study would be: [*Describe exclusion, if any. Note: exclusion criteria are a set of criteria that indicates the qualities a participant cannot in order to continue study participation, which often involves post-consent screening procedures. This does not refer to which participants’ data will be excluded from data analysis*.]

## **Study Duration:**

Participation in this study is expected to take…[*Explain the duration of the study, which includes the number of sessions as well as time spent actively participating*.]

## **Risks:**

Potential risks related to being in this study may include…[*Explain any risks of harm to participants, which can includes criminal or civil liability, damage to participants’ financial standing, employability, educational advancement, or reputation.*]

or

The researchers do not anticipate any risks beyond what could occur in daily life [*if the procedures involve sensitive items, it is helpful to add: ‘(including the recall of thoughts and behaviors that could trigger negative emotions, elicited either internally or by external stimuli that are part of ordinary daily experience. Although breech of confidentially could be a risk given the potentially sensitive nature of some of the questions, there are protections in place that make this possibility unlikely.)*’]

## **Benefits:**

Participants may benefit from taking part in this study. Specifically,…[Explain any direct benefits to the participants.]

or

Participants will not directly benefit from taking part in this study. [Optional: Explain any benefits of the potential research outcomes.]

## **Compensation:**

As compensation for their time, participants will receive…[Explain whether or not there will be any compensation associated with research participation, monetary or otherwise.]

or

Participants will not receive any compensation for taking part in this study.

[*Compensation should not be coercive – at a level that puts undue pressure on potential participants or convinces them to participate when they otherwise would not want to.*]

## **Confidentiality [*and Anonymity if appropriate*]:**

All data collected from participants will be kept confidential. Only the researchers mentioned above will have access to participant responses, which will be kept in a secure location. All information will be presented or published in group form and will not contain any identifying information or link any individual participant with the data.

[*Add any additional confidentiality or anonymity information IF relevant. Examples may include: ‘All data will be collected anonymously’, ‘Participants’ names will not be connected to any responses provided, and responses cannot be directly identified’, ‘Any identifying information, such as this signed consent form, will be stored separately from any other data’, ‘All participants will be given a code/pseudonym to ensure that names will not be associated with any data’, ‘Coding documents that include identifying information will be stored separately from any data’, ‘Coding documents with identifying information will be shredded/deleted as soon as data is linked, so that participant identities cannot be linked to the data’, ‘Potentially identifying email addresses will be collected separately and shuffled before participant data is accessed so that they cannot be used to indirectly link participant responses to their identities’, ‘Any identifying information will be shredded/deleted after 3 years’, ‘De-identified data will be kept indefinitely’, etc.*]

## **Contact Information for Questions or Concerns:**

You have the right to ask any questions you may have about this research. If you have any question or concerns, please contact [*PI or Faculty Supervisor name/contact info.*] or [*Associate/Student researchers name/contact info.*]. If you have other concerns about this study or would like to speak with someone not directly involved in the research, or if you have questions regarding your rights as a human subject or would like to make a complaint, please contact the Daemen University Institutional Review Board (IRB) Chair at irb@daemen.edu.

## **Voluntary Consent:**

Please review all the information on this form before deciding whether or not you would like to participate. Taking part in this research study is strictly voluntary. If you choose to take part, you have the right to stop at any time or skip any part of the research that you may wish. If you do not wish to participate, you are free to leave [*or ‘you may exit this site’, ‘please disregard this email’, etc.*]

If you wish to participate, please sign below [*or ‘please click the ‘I agree’ button below’ for an online study*]. By signing below [*by* *clicking ‘I agree’ below*], you are attesting that you have read the above information, that you understand the tasks and risks associated with the study, and that you have had the chance to ask any questions that you may have and that you are aware that you can contact the researchers now or in the future if concerns arise. By signing below, you are attesting that you understand that your participation is entirely voluntary and that you can choose to discontinue your participation at any time. By signing below, you are attesting that you are at least 18 years of age. Lastly, by signing below, you are providing your consent to participate in this study.

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Printed name of participant Signature of participant Date

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Printed name of researcher Signature of researcher Date

[*I agree*

*I do not agree*]

Please keep a copy of this document for your records. [*Please print a copy of this document for your records*.]

**[*Optional Sections to Include if Relevant*]**

## **Costs:**

There are costs associated with being a participant in this study. [*Explain any costs (e.g., travel, medial, material, etc.) incurred upon individuals related to being a participant in the study.*] or

There are no costs associated with being a participant in this study.

## **Reimbursement for Medical Treatment:**

Daemen University, its agents, or its employees do not compensate for or provide free medical care for human subjects/participants in the event that any injury or harm results from participation in a human research project. In the unlikely event that you become ill or injured as a direct result of participating in this study, you may receive medical care or treatment, but it will not be free of charge even if the illness or injury is a direct result of your participation. [*Must be included for studies that are greater than minimal risk*]

## **Disclosure of Appropriate Alternative Procedures/Treatment:**

Before deciding whether or not to participate in this study, it is important that you are aware of the alternative procedures/treatments available to you.

[*Prospective subjects must be informed of the care they would likely receive if they choose not to participate in the research. This includes alternatives such as approved therapies for the patient's condition, other forms of therapy (e.g., surgical), and when appropriate, supportive care with no disease-directed therapy. This disclosure must include a description of the currently recognized standard of care.* *This statement must be included for studies in which there are demonstrated alternative treatments or procedures, aside from those used in the study, that might be advantageous to the subject.*]

## **Use of Data for Future Research:**

The private identifiable information or identifiable biospecimens provided by participants as part of this study may be de-identified, and after removing identifiable information may be used for future studies or distributed to another investigator for future research studies without additional informed consent from the participant or their legally authorized representative.

or

The private identifiable information or identifiable biospecimens provided by participants as part of this study, even if de-identified, will not be used for future studies or distributed to another investigator for future research studies.

[One of the above *must be included for studies that collect private identifiable information or identifiable biospecimens.*]

## **Contact for Follow-up Information:**

Participants may give their permission to be contacted to participate in follow-up studies or questions/interviews. If you wish to be contacted, please provide your contact information below. Any contact information you provide will be kept confidential and stored separately from any data that you may provide as a participant in this study.

I agree to be contacted for a follow-up [*email/phone call/ interview/study opportunity*]

[*Phone number/Email*]: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Printed name of participant Signature of participant Date

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Printed name of researcher Signature of researcher Date