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| **Daemen University IRB – Human Subjects Research**  **Application for Certification of Exemption** | | | | | | | | | | | | | | | | | | | | |
| **INSTRUCTIONS**  **Before completing this form, researchers the faculty supervisor (if student researchers are involved) must be sure the proposal meets the criteria for Certification of Exemption. If either are unsure of the criteria, please see a description of each type of review on Daemen’s Institutional Review Board - Human Subjects Research (IRB) website. If your project meets the criteria for Certification of Exemption, it will be reviewed as such. If not, it will need to be resubmitted using an application for Expedited/Full Review protocols, which may delay the review of your protocol. It is best to plan accordingly in case you categorize into the wrong review type.**  **As you complete the form, please be sure to *read the directions for each section thoroughly and provide relevant and detailed responses where applicable*. In addition, be sure to *append all relevant study materials to the end of this document in the order in which they are referred to within the document, and in the manner in which they will appear to participants*. Lastly, when the form is complete, be sure that all researchers sign the form (use electronic signatures or type names), and *submit an electronic version with all supporting materials/appendixes in a Single MSWord file to the IRB Chair at*** [***irb@daemen.edu***](http://irb@daemen.edu)**. Please copy (cc) all associate investigators and use Daemen University e-mail addresses (where applicable). For student projects, faculty supervisors must submit on behalf of the student researcher(s).** | | | | | | | | | | | | | | | | | | | | |
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| **I. Complete All Items Below:** | | | | | | | | | | | | | | | | | | | | |
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| **Type of Proposal *(Please check one)*:** | | | |  | | **New** | | |  | **Resubmission with Requested Revisions1** | | | | | | | |  | | |
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| **1 If a resubmission with requested revisions, please either use *track changes* or *highlight in yellow* all new changes from the original submission (or the most recent resubmitted version) and indicate date of current submission below.** | | | | | | | | | | | | | | | | | | | |  |
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| **Date Submitted to IRB:** | [Date of Submission] | | | | | | | | | | | | | | | | | | | |
| **Principal Investigator:** | [Name of Principal Investigator or Student responsible for the project and correspondence] | | | | | | | | | | | | | | | | | | | |
| **Title of above:** |  | Dr. |  | | Mr. | |  | Mrs. | | |  | Miss |  | Ms. |  | Other: |  | |  | |
|  |  | |  |  |  |  |  | | | |
| **Daemen e-mail address:** |  | | | | | | | | | | | | | | | | | | | |
| **Phone:** |  | | | | | | | | | | | | | | | | | | | |
| **Associate Investigator(s):** | [Full name of each investigator other than the Principal] | | | | | | | | | | | | | | | | | | | |
| **Daemen e-mail addresses (where applicable):** |  | | | | | | | | | | | | | | | | | | | |
| **Course:** | [Course for which any students are conducting research] | | | | | | | | | | | | | | | | | | | |
| **Faculty Supervisor:** | [Name of faculty member(s) overseeing research — required for all student research projects] | | | | | | | | | | | | | | | | | | | |
| **Campus Address:** |  | | | | | | | | | | | | | | | | | | | |
| **Daemen e-mail address:** |  | | | | | | | | | | | | | | | | | | | |
| **Phone:** |  | | | | | | | | | | | | | | | | | | | |
| **Title of Project:** | *[Does not have to match title on consent if it reveals expected results or might otherwise bias responses]* | | | | | | | | | | | | | | | | | | | |

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| **II. Please Indicate with an “X” All Applicable Conditions Below:** |

*(In order for the research to be considered exempt, one of the following five main criteria below (and corresponding sub-criteria where applicable) must be met)***:**

**1) Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices, such as (i) most research on regular and special education instructional strategies, or (ii) research on the effectiveness of or comparison among instructional techniques, curricula, or classroom management methods. The research is not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. The exemption may only be used for studies regarding normal educational practices in which the subjects are the students of the principle/associate investigators*. \*45 CFR §46\_\_\_\_.104(d)(1)***

In the box below, please provide a brief description of the research background, design, and procedures with sufficient detail to justify the category of exemption above. List and append any relevant materials to the end of this form.

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**2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement) or research involving survey or interview procedures or research involving observation of public behavior (including visual and/or auditory recording). *\*45 CFR §46\_\_\_\_.104(d)(2)***

\*Note: Surveys cannot include collection of bio specimens.

\*Note: Research is not exempt under Category 2(iii) if subjects are under 18, but research can be considered exempt under Category 2 (i and ii) if the research involves only educational tests or observation of public behavior during which the investigator does not participate in the activities being observed.

*(In order for the research to be considered exempt under this category, one of the following additional criteria below must be met - please place an x next to any of the conditions below that are true).*

\_\_\_\_\_\_\_(i). Information obtained is recorded in such a manner that the identity of the human subjects cannot readily be ascertained, directly or indirectly through identifiers linked to the subjects.

\_\_\_\_\_\_\_(ii). Information obtained can be identified directly or indirectly, but any disclosure of the human subjects’ responses outside of the research would not reasonably place subjects at risk of harm (i.e., risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, education advancement or reputation).

\_\_\_\_\_\_\_(iii). Information obtained can be identified directly or indirectly and disclosure could put the subjects at risk of harm, but the researcher can document that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.

\*Note: Exempt research under Category 2 (iii) will be subject to limited review.

In the box below, please provide a brief description of the research background, design, and procedures with sufficient detail to justify the category of exemption above (e.g., describe the consent procedures, describe how the data will be non-identifiable (either directly or indirectly), or describe how disclosure outside of the research process would not put the subject at harm, and how you will protect privacy and confidentiality. List and append any relevant materials (e.g., recruitment materials, educational tests, survey or interview items, and consent forms), to the end of this form.

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**3A) Research involving benign behavioral Interventions in conjunction with the collection of information from adult subjects through verbal or written responses or audiovisual recordings, if the subject prospectively agrees to the study procedures (i.e., participants consent to the interventions). *\*45 CFR §46\_\_\_\_.104(d)(3)(i)***

\*Note: Research is not exempt under Category 3A if subjects are under 18.

*Benign behavioral interventions are defined as “brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing”*

*(In order for the research to be considered exempt under this category, one of the following additional criteria below must be met - please place an x next to any of the conditions below that are true).*

\_\_\_\_\_\_\_(i). Information obtained is recorded in such a manner that the identity of the human subjects cannot readily be ascertained, directly or indirectly through identifiers linked to the subjects.

\_\_\_\_\_\_\_(ii). Information obtained can be identified directly or indirectly, but any disclosure of the human subjects’ responses outside of the research would not reasonably place subjects at risk of harm (i.e., risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, education advancement or reputation).

\_\_\_\_\_\_\_(iii). Information obtained can be identified directly or indirectly and disclosure could put the subjects at risk of harm, but the researcher can document that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.

\*Note: Exempt research under Category 3A (iii) will be subject to limited review.

In the box below, please provide a brief description of the research background, design, and procedures with sufficient detail to justify the category of exemption above (e.g., describe the consent procedures, describe the behavioral interventions, describe how the data will be non-identifiable (either directly or indirectly), or describe how disclosure outside of the research process would not put the subject at harm, and how you will protect privacy and confidentiality. List and append any relevant materials (e.g., intervention directions/materials, any tests, surveys or interview items, recruitment materials, and consent forms), to the end of this form.

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**3B) Research involving benign behavioral Interventions in conjunction with the collection of information from adult subjects through verbal or written responses or audiovisual recordings in which the subjects are deceived regarding the nature or purposes of the research, if the subject prospectively agrees (i) to the study procedures and (ii) that they will be unaware of or misled regarding the nature or purpose of the research (i.e., participants consent to the interventions and that they will be misled). *\*45 CFR §46\_\_\_\_.104(d)(3)(iii)***

\*Note: Research is not exempt under Category 3B if subjects are under 18.

*Benign behavioral interventions are defined as “brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing”*

*(In order for the research to be considered exempt under this category, one of the following additional criteria below must be met - please place an x next to any of the conditions below that are true).*

\_\_\_\_\_\_\_(i). Information obtained is recorded in such a manner that the identity of the human subjects cannot readily be ascertained, directly or indirectly through identifiers linked to the subjects.

\_\_\_\_\_\_\_(ii). Information obtained can be identified directly or indirectly, but any disclosure of the human subjects’ responses outside of the research would not reasonably place subjects at risk of harm (i.e., risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, education advancement or reputation).

\_\_\_\_\_\_\_(iii). Information obtained can be identified directly or indirectly and disclosure could put the subjects at risk of harm, but the researcher can document that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.

\*Note: Exempt research under Category 3B (iii) will be subject to limited review.

In the box below, please provide a brief description of the research background, design, and procedures with sufficient detail to justify the category of exemption above (e.g., describe the consent procedures including how subjects will be informed of the deception, describe the behavioral interventions, describe how the data will be non-identifiable (either directly or indirectly), or describe how disclosure outside of the research process would not put the subject at harm, and how you will protect privacy and confidentiality. List and append any relevant materials (e.g., intervention directions/materials, any tests, surveys or interview items, recruitment materials, and consent forms), to the end of this form.

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**(4) Research involving secondary research for which consent is not required (e.g., existing data, documents, records, pathological specimens, or diagnostic specimens. *\*45 CFR §46\_\_\_\_.104(d)(4)***

*(If the data consist of identifiable or private information or biospecimens, in order for the research to be considered exempt under this category, one of the following additional criteria below must be met - please place an x next to any of the conditions below that are true).*

\_\_\_\_\_\_\_(i). The data are publicly available.

\_\_\_\_\_\_\_(ii). Information obtained is recorded in such a manner that the identity of the human subjects cannot readily be ascertained, directly or indirectly through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not attempt to re-identify subjects.

In the box below, please provide a brief description of the research background, design, and procedures with sufficient detail to justify the category of exemption above (e.g., describe the nature of the secondary research and how the investigator has access to the data, describe how the data will be non-identifiable (either directly or indirectly), or that the data are publicly available, and how the investigator will protect privacy and confidentiality. List and append any relevant materials (e.g., permission letter to access the data – Note: letters of agreement must be submitted on official letterhead and contain an original signature, and it must be explained how the individual granting permission has the authority to do so).

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**5) Research involving taste and food quality evaluations and consumer acceptance studies. *\*45 CFR §46\_\_\_\_.104(d)(6)***

*(In order for the research to be considered exempt under this category, one of the following additional criteria below must be met - please place an x next to any of the conditions below that are true).*

\_\_\_\_\_\_\_(i). The consumption only includes wholesome foods without additives.

\_\_\_\_\_\_\_(ii). The consumption includes ingredients at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food and Safety Inspection Service of the U.S. Department of Agriculture.

In the box below, please provide a brief description of the research background, design, and procedures with sufficient detail to justify the category of exemption above (e.g., describe the nature of the taste study and justification of food safety). List and append any relevant materials.

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| **\*\*Compliance with HIPAA and FERPA Privacy Regulations\*\***  It is expected that all studies approved by the Daemen University IRB comply with federal regulations including HIPAA and FERPA.  In accordance with the provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), investigators shall respect the confidential nature of all information that they may have access to, including but not limited to the subjects’ personal health information provided to them orally or contained in medical records in written or electronic form. If your study involves information derived from electronic medical records, a HIPAA authorization is required in addition to an informed consent document.  Additionally, in accordance with the provisions of the Family Educational Rights and Privacy Act (FERPA), investigators shall respect the confidential nature of any student education records and may not disclose this information or access it without consent unless they have a legitimate educational interest. |
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| **III. CERTIFICATION:**  This form must be signed (either by typing in your name or inserting an electronic signature) and submitted to the IRB Chair (irb@daemen.edu) with a copy (cc) to all investigators on the protocol using daemen.edu addresses (where applicable).  The signatures below indicate that both the researcher(s) and the faculty supervisor (if student researchers are involved) will operate in accordance with the details in this protocol and all professional, federal, and Daemen University regulations governing research involving human subjects as stated in the IRB guidelines for the protection of human subjects. |
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| ***I (we) certify that the information in the project identified above is true to the best of my (our) knowledge.***  ***I (we) certify that this research project will NOT commence without first receiving a letter of IRB approval from the Chairperson of the Daemen University IRB.***  ***I (we) certify that, when approved, the project identified above will not be changed without filing a Study Modification Form and receiving IRB approval.***  ***I (we) certify that I (we) completed the CITI training and have read a description of each type of review on the IRB website and that this protocol meets the requirements for a Certification of Exemption as stated on the website.***  ***I (we) certify that I (we) will follow all of the details outlined in the study protocol as approved by the IRB during the period of the research project.***  ***I (we) certify that I (we) will maintain all records of this research as required by the Daemen University IRB, submit a Study Closure Form at the conclusion of this study, and will report any adverse reactions or subject complaints within 48 hours to the Chair of the IRB.*** |

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| Researcher’s Signature: |  | Date: |
| ***In addition, the faculty supervisor’s signature indicates he or she has reviewed the entire proposal and endorses it.*** | | |
| Faculty Supervisor’s Signature: |  | Date: |

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| Associate Investigator’s Signature: |  | Date: |
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