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| **Daemen University IRB – Human Subjects Research****Application for Full or Expedited Review**  |
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| **INSTRUCTIONS****Before completing this form, researchers and the faculty supervisor (if student researchers are involved) must complete the checklist below to determine if the protocol can be considered for Expedited Review or if it must be sent for Full Review. 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 Expedited Review, it will be reviewed as such. If not, it will be sent to the committee for Full Review. However, Full Review protocols must be received at least 10 business days in advance of the meeting date, so it’s 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***](hsrrc.chair%40daemen.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).** |
| **I. Complete All Items Below:** |
|  |  |  |  |  |  |  |
| **Type of Proposal *(Please check one)*:** |  | **New** |  | **Resubmission with Requested Revisions1** |
|  |
| **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.** |  |
|  |
| **Review Requested *(Use checklist below)*:**  |  | **FULL** |  | **EXPEDITED** |
|  |
| **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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| **Minimal Risk Checklist****If any of the following are true, your proposal constitutes greater than minimal risk and requires *Full Review*:** |
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|  | **YES** |  | **NO** |  |  |  |

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| 1. |  |  |  |  |  | Will the proposed project subject participants to more than minimal risk? **Minimal Risk** is defined by the probability and magnitude of harm or discomfort anticipated in the research that is not greater than would be ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests. *\*45 CFR* ***§****\_\_\_\_****.****104(d)(1)* |
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| 2. |  |  |  |  |  | Will participants be subjected to physical discomfort, pain, aversive stimuli, or the threat of any of these more so than they would in their daily life? If YES, HIGHLIGHT all that apply. |
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| 3. |  |  |  |  |  | Does the investigation use procedures designed to induce embarrassment, humiliation, lowered self-esteem, guilt, conflict, anger, discouragement, or other emotional reactions more so than would occur in daily life? If YES, HIGHLIGHT all that apply. |
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| 4. |  |  |  |  |  | Will participants engage in unaccustomed physical activity (i.e., any physical activity that is more strenuous than they would encounter in their daily life)? |
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| 5. |  |  |  |  |  | Will participants be deceived (actively misled) without providing prospective agreement to being unaware of the deception or mislead regarding the nature or purpose of the research? |
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| 6. |  |  |  |  |  | Will participants be exposed to electromagnetic radiation (X-rays), lasers, surgery, drugs, or chemicals?  |

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| 7. |  |  |  |  |  | Will the research involve the collection of blood samples or other bodily fluids in any amount?  |
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| 8. |  |  |  |  |  | Will the research procedures involve exposing vulnerable subjects to any kind of intervention or manipulation that would put them at risk more so than they would experience in daily life? **Vulnerable subjects** are defined as those who are vulnerable to coercion or undue influence such as minors (i.e., individuals under the age of 18), prisoners, individuals with impaired decision-making ability, or economically or educationally disadvantaged persons. If YES, HIGHLIGHT all that apply. |
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| 9. |  |  |  |  |  | Will participants experience any physical or psychological harm more so than they would in their daily life that has not been indicated above? If YES, briefly explain below and carefully outline such procedures in the **Description of the Research Plan** in this application) |
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| **II. Funding:**  |
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| 1. | Please identify all sources of the funding for the present study: |
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|  |  | Unfunded |  |
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|  |  | Governmental Agency/ies: |  |
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|  |  | Foundation(s): |  |
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|  |  | Corporation(s): |  |
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|  |  | Organization(s): |  |
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|  |  | Daemen University Administrative Office: |  |
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|  |  | Daemen University Department: |  |
|  |
|  |  | Individual(s): |  |
|  |
|  |  | Other: |  |
|  |
| 2. | Is this proposal part of a grant? |  | Yes |  | No |
|  |
|  | If YES, please answer the following questions: |
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|  | a. | Name of grant: |  |
|  |
|  | b. | Name of institute or agency that awarded the grant: |  |
|  |  |  |  |
|  | c. | Principal Investigator listed on the grant: |  |
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| **III. Coordination with other Institutions:**  |
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| 1. | Will this proposal involve the coordination with any other institution (e.g., recruitment, location, participants)? *Note: If coordination is required, a signed letter of agreement must be appended to this application. 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. The letter should be written so that IRB has a record that the institution acknowledges an understanding of general protocol/recruitment procedures (these should be briefly included in the letter) and must specifically indicate approval to recruit and/or conduct the study at the location.* |
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|  |  | Yes |  | No |
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|  |  | If yes, please discuss the nature of this coordination and indicate the name of the institution(s): |  |
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| 2. | Has this proposal been or will it be submitted to other Human Subjects Review Boards (IRB Committees), departmental committees, or community agencies for review and approval? *Note: according to 45 CFR* ***§****\_\_\_\_****.****114, cooperative research must rely on a Single IRB unless it is indicated that the research is not subject to the provision. Typically, if Daemen participants are involved, Daemen should be the lead IRB.* |
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|  |  | Yes |  | No |
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| **IV. Location of Research:** |
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| 1. | Where will research be physically conducted?*(If online, indicate relevant platforms/websites)* |  |
|  |  |
| **V. Participants:**  |
|  |  |
| 1. | Types of participants and controls: |
|  | a. | Please check if you are planning to study any of the following vulnerable populations: |
|  |  |
|  |  |  | Minors |  | Prisoners |  | Economically Disadvantaged Individuals |  | Educationally Disadvantaged Individuals |
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|  |  |  | Individuals with Impaired Decision-Making Ability |  | Other:  |
|  |  |  |
|  | b. | Age range of participants: |  |
|  |  |  |  |
|  |  c. | Estimated sample size: |  |
|  |  |  |  |
|  | d. | Population from which participants will be derived: |  |
|  |  |  |  |
|  | e. | Inclusion criteria for participants and controls:*(This refers to inclusion criteria for participation in the study, not criteria for inclusion in data analysis)* |  |
|  |  |  |  |
|  | f. | Exclusion criteria for participants and controls:*(Include any restrictions in addition to inclusion criteria (i.e., those specifically excluded from participation, not the opposite of inclusion criteria)* |  |
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| 2. | Recruitment: |
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|  | a. | Describe the **specific steps** to be used to identify and recruit prospective participants. Recruitment telephone and/or e-mail scripts and advertisements must be appended to the end of this application: |
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|  | b. | Describe how you have permission to access to potential participants or explain why permission is not needed: |
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| 3. | Will this project utilize post-consent screening procedures (e.g., for inclusion or exclusion purposes)? *Note: Screening cannot take place prior to the consent process.* |
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|  |  |  | Yes |  | No |
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|  |  | If yes, describe any screening procedures you will use and how the results of your screening procedures will identify those who are eligible to continue participating (e.g., those who meet inclusion criteria), and identify persons who are ineligible and whose participation will be discontinued (e.g., those who meet exclusion criteria). |
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| 4. | Will participants be compensated in any way (e.g., for time or travel) for their participation? |
|  |  |  | Yes |  | No |
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|  | If yes, please explain below how and when the participants will be compensated. |
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| **VI. Study Duration:** |
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| 1. | Expected duration of study (e.g., March 2020 – May 2020): |  |
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|  | ***If this protocol is approved, the approval is for a period of time NOT to exceed one year from the date of the approval. Researchers are required to submit a Modification Form to request a renewal for all research protocols that will exceed one year, or to reopen a previously closed protocol. Additionally, the Principal Investigator is responsible for providing the IRB with findings and/or notification of the status of the research at the completion of the project (i.e., Study Closure Form).*** |
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| 2. | Total expected time commitment of each participant: |  |
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| **VII. Description of the Research Plan:**  |
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| 1. | Project Background: Please include (1) a ***brief*** background summary of the literature, (2) the importance of or need for the study, (3) the study purpose, and (4) study hypotheses. Include a reference list and cite work where appropriate. |
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| 2. | Please describe your study design (e.g., experimental and control conditions, etc.) and identify your variables (e.g., independent/predictor variables and dependent/outcome variables, etc.) if applicable: |
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| 3. | Informed Consent/Assent |
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|  | The consent form must be written in age-appropriate language (i.e., 8th grade level for adult participants) and use wording that is easily understandable to those outside your area of expertise. In the case of vulnerable participants, consent must be obtained from appropriate legally authorized representative(s). Please be sure the consent form contains the minimal necessary information as required by the Daemen University IRB (see IRB website).Please note that all procedures must be included in the consent form unless deception is planned. If deception is planned, whenever possible, participants should prospectively agree to being unaware of or misled regarding the nature and the purpose of the research.Assent is also required for minors and individuals with impaired decision-making ability (in addition to consent of the appropriate legally authorized representative). Assent language must also be age-appropriate, *which varies* depending on the age of the minor (e.g., an assent for a 15-year old participant will use older language than an assent for 7 year-old participants). As a general rule, written documentation of assent should be obtained for minors 7 years of age or older.  |
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|  | a. | In the box below, list the individual name(s) of each researcher who will obtain consent (signed or otherwise) from study participants: |
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|  | b. | Are you requesting a waiver of signed (written or electronic) informed consent? |  | YES |  | NO (If "NO", skip to item c. below) |
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|  |  | **If you answered "YES"** (to 3b), please justify this request: *Note: Waiver of signed consent is justifiable if (1) the only record linking the subject and the research would be the informed consent form, and the principal risk would be potential harm resulting from a breach of confidentiality, (2) the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context, (3) if the subjects or legally authorized representatives are members of a distinct culture group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to the subjects, and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.* |
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|  |  | **If you answered "YES"** (to 3b), please explain the process of how and when you will obtain and otherwise document informed consent in the absence of signed informed consent (e.g., providing an online consent sheet or oral consent procedures) and how you will ensure that participants fully understand the study: |
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|  | c. | **If you answered “NO”** (to 3b; i.e., you are NOT requesting a waiver of signed consent), please explain the process of how and when you will obtain signed informed consent and how you will ensure that participants fully understand the study: |
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| 4. | Procedures and Materials |
|  | a. | Please describe your full methodology, step by step, specifically referencing each of the materials that participants are exposed to throughout the study (e.g., surveys, tests, questionnaires, stimuli, and/or instruments).  |
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|  | b. | Please describe each of the materials that participants are exposed to throughout the study. Append these materials along with the instructions that will be given to participants, in the manner that they will be presented to participants and in the order in which they will appear. If a measure that is used that is not retrievable in the public domain, please also append appropriate permission. |
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|  | c. | Please list below each appendix that relates to the materials described above, including the title of each, following the examples below. |
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|  |  | Appendix X. *[Please Type in Descriptive Title Here]* Appendix Y. *[Please Type in Descriptive Title Here]*Appendix Z. *[Please Type in Descriptive Title Here]* |
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| 5. | Deception |  |
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|  | a. | Does the protocol involve any deception?  |  | Yes |  | No |  |  |
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|  | b. | If YES (to 5a), please fully describe the debriefing process and append a copy of the debriefing script: |
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|  | c. | If YES (to 5a), will participants have prospectively agreed to the deception during the consent process?  |
|  |  |  |  | Yes |  | No |  |  |
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|  | d.  | If NO (to 5c; i.e., participants have not prospectively agreed to the deception), please justify why the deception is necessary: |
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| 6. | Risks and Benefits: *Please note that expedited proposals, by definition, should not carry more than minimal risk.* |
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|  | a. | Please list and describe any real or perceived risk (e.g., physical, psychological, economic and/or social) to participants. Each of these risks needs to also be presented during the consent process. If this is an Expedited Protocol, please justify why these risks are no greater than minimal: |
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|  | b. | Describe the procedures and precautions that will be taken to minimize or avoid each of these risks (to the extent it is possible): |
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|  | c. | Please list and describe any real benefits to the participants: |
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|  | d. | If appropriate, describe any withholding of normal treatment and/or alternative treatments: |
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|  | e. | Explain the conditions under which you would discontinue the participation of any or all participants: |
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|  | ***In the case of an unexpected and/or serious adverse event you must do the following:*** |
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|  | a. | Immediately report the event by telephone to the Chair of the IRB. |
|  | b. | Terminate the research project if there has been serious harm to subjects. |
|  | c. | Submit a written report of the event to the Chair of the IRB within three (3) working days. |
|  | d. | In some circumstances you may be required to report any adverse events to the sponsoring agency and the appropriate state and federal agencies. |
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| **VIII. Privacy, Confidentiality, & Data Management:**  |
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|  | a. | *Participant Privacy:* When *gathering* data, what measures will you take to protect your participants’ privacy *during* the study? Examples include interviewing subjects individually in a closed room, interviewing over the phone, surveying participants using dividers or empty seats between them, or using online data collection platforms such as SurveyMonkey or Google Forms, etc. |
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|  | b. | *Participant Confidentiality:* Will any identifying information (name, email, date of birth, voice/video recordings, company working for, etc.) or protected academic or health information (for example, anything protected by FERPA or HIPPA, such GPA, transcripts, disease diagnoses, medical information) be collected from participants or their records?*Note: if you are obtaining signed consent or collecting email addresses, you will have to check "YES" for identifying information. If you are collecting any information protected by FERPA or HIPPA, you will have to check "YES" for protected information.* |
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|  |  | Identifying Information: |  |  | YES |  | NO |  |
|  |  |  |
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|  |  | Protected Information: |  |  | YES |  | NO |  |
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|  | c. | Please describe the methods of protecting confidentiality (i.e., protecting the identity and responses of participants) ***prior to, during, and after*** data are collected. Describe in detail how all data will be handled so that participants’ identities and data remain confidential. For example, how will any coding systems be protected so others can’t like participants’ data with their identities, how will any video and audio recordings be handled (e.g., how/when will recordings be transcribed and the original recordings deleted, etc.), and how will any written or electronic responses be handled (e.g., written responses are placed in a sealed envelope/lock box, electronic responses are password protected and do not collect IP or email addresses, and are downloaded to a secure device and deleted from the online platform, etc.) *Note:* *Presentations/publications (including theses/dissertations) must not contain any information that would reveal the identities of participants.* |
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|  | d. | *Data Storage:* |
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|  |  | 1. | How long will you store your data?*Note: Raw data and consent documents (if applicable) must be stored for a minimum of 3 years per federal regulations. However, data should be deidentified whenever possible.* |  |
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|  |  | 2. | Where (physically) will you store your data ***during and after*** data collection? Please be specific (e.g., video/audio recordings will be stored on a computer during data collection and in a locked cabinet after transcription, or electronic responses will be stored in the online platform during data collection but on a password protected computer after data collection, etc.) *Note: After the project is complete, all data from student research studies should be stored only with the faculty supervisor for the remainder of the storage period.* |
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|  |  | 3. | Other than the investigators listed on this application, please explain who will have access to the *raw data* and under what circumstances, and how you will protect the data from unauthorized access. |
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|  |  | 4. | Describe specifically how will you dispose of/destroy your data at the end of the 3-year (minimum) storage period.  |
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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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| **IX. 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. |
|  |
| ***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 appropriate requirements for the level of review stated on the website.******I (we) certify that I (we) will follow all of the details outlined in the study protocol and the method of obtaining informed consent 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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| Principal Investigator’s Signature: |  | Date: |
| ***In addition, the faculty supervisor’s signature indicates he or she has reviewed the entire protocol and endorses it.*** |
| Faculty Supervisor’s Signature:  |  | Date: |

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