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| akleinschmit@dbq.edu\\Facwinfile\FACUSERS\JSupple\My Documents\My Pictures\ud letterhead.jpg |  INSTITUTIONAL REVIEW BOARD (IRB) |

 **APPLICATION FOR HUMAN SUBJECTS RESEARCH PROJECTS**

**FOR IRB COMMITTEE USE ONLY**

**Term/Year:  Project Identification Number: **

1. **PROJECT OVERVIEW**

**Principal Investigator (PI)**

Name:  Title: 

Institution:  Department: 

Email:  Phone: 

Mailing Address: 

Credentials of PI related to project: 

**Coinvestigators and/or any other key personnel involved in the research:**

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**Faculty Advisor (if student)**

Name:  Title: 

Institution:  Department: 

Email:  Phone**: **

Credentials of Advisor related to project: 

Course Name and Number (for students if applicable): 

**Proposed Project Title: **

**Project Start and End Dates**: 

**Project Location (where work will be done):** 

**Project Description (provide a one paragraph description of your project or study)**

**

Project Type (X those that apply)**

 Faculty Research  Thesis or Dissertation

 Student Individual Research (under faculty direction)  Student Class Project (under faculty direction)

 Grant Funded Application  Other

*Name and source of grant, plus relevant grant deadlines Specify*

 

**Research Subjects (general population)**

Check (X) all that apply and estimate the total number of individuals in each relevant category about whom you will be collecting data for your project or study. If none are relevant, leave blank.

 College Students #   General Public # 

College Faculty #   Other # 

 College Staff #  *Specify* 

**Research Subjects (special/vulnerable populations)**
Check (X) all that apply and estimate the total number of individual in each relevant category about whom you will be collecting data for your project or study. If none are relevant, leave blank.

Individuals who

 Are under age 18 #   Are elderly # 

 Have intellectual disabilities #   Are imprisoned # 

 Have physical disabilities #   Are economically disadvantaged # 

 Are pregnant #   Other # 

 Have language barriers #  *Specify* 

**COVID-19 Mitigation Strategies Associated with Data Collection**

Data Collection Modality:

 Virtual Data Collection (e.g., electronic survey, video-conference meeting)

 Face-to-Face Data Collection

If you have chosen “Face-to-Face Data Collection,” explain why “Virtual Data Collection” would not work within the framework of our research.

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Categorize any proposed Face-to-Face research data collection based on the following risk categories

 **High-risk** face-to-face data collection is generally restricted at UD. High-risk face-to-face data collection means a high potential for exposure to known or suspected sources of COVID-19, including:

* Aerosol-generating procedures
	+ Exercising (e.g., maximal oxygen uptake)
	+ Inducing cough, sneeze, or strong exhale (e.g., spirometer)
* Specimen collection that may generate a cough or a sneeze
* Contact with individuals who have or were exposed to COVID-19

 **Medium risk** face-to-face data collection is potentially restricted at UD. The ability to engage in medium risk face-to-face data collection is dependent on the degree of risk and the researcher’s ability to mitigate the risk. Researchers should contact the IRB Chair before submitting their IRB to determine feasibility.

* Medium exposure risk includes frequent or close contact with people who are neither known nor suspected of being infected with COVID-19, including:
	+ Specimen collection
	+ Interaction with the general public
		- Interviews
		- Survey collection

 **Low-risk** face-to-face data collection is generally unrestricted at UD, but researchers are required to seek IRB approval and outline mitigation strategies as needed.

* Low exposure risk includes neither contact nor close contact with people who are known or suspected of being infected with COVID-19, including:
	+ Secondary data
	+ Data already collected for a different purpose
		- Typical classroom activity
		- Typical weight-room activity

**Describe your data collection protocol, highlighting precautions that will be taken to reduce the likelihood of transmitting COVID-19:**

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1. **DETERMINING REVIEW STATUS: Exempt, Expedited, or Full**

**BASIC REQUIREMENTS FOR EXPEDITED REVIEW OR EXEMPTION – check (X) all that apply**

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|  | **Research Subjects: no special/vulnerable populations**Subjects are at least 18 years of age and research is not focused on members of a vulnerable group (see page 2). |
|  | **Research Risk: minimal to none**Research places human subjects at minimal or no risk of physical, psychological, social, spiritual, mental, social, professional, or economic harm or liability, and does not report criminal behavior. |
|  | **Sensitive Topics: none**Subjects will not be asked questions regarding sensitive topics, such as, but not limited to, drug use, sexual behavior, abuse history, health conditions, religious beliefs and/or practices. |
|  | **Data Collection: without manipulation or deception**Public observation of behavior and researcher participation (if any) is done without manipulating the environment to add stress to elicit behavioral response. The subjects are not intentionally deceived in any way to elicit responses or data. |
|  | **Data Safety: confidential and secure**The data collected will be either untraceable to the subject or, if traceable, not harmful. All data will be maintained in a secure location and maintained for five years or other length of time as required by federal, state, or local laws. |
|  | **Consent: Informed and/or Implied**If individual identifiers are collected from human subjects, informed consent will be obtained. If no individual identifiers are collected from human subjects, implied consent will be obtained. |
|  | **COVID-19 Mitigation Strategies:** virtual data collection or low/medium risk with F2F collectionData collection protocol highlights precautions that will be taken to reduce the likelihood of transmitting COVID-19. |

**HUMAN SUBJECTS RESEARCH PROTECTION EXEMPTION CATEGORIES – check (X) all that apply**

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|  | **Exemption I (educational practices)**Research is conducted in established or commonly accepted educational settings, involving normal educational practices common to the subject area and course level (e.g., research on the effectiveness of or the comparison among educational instructional strategies and techniques, curricula, or classroom management methods. |
|  | **Exemption II (non-identifiable tests, surveys, interviews, observations)**Research involving the use of survey, interview procedures, educational tests (cognitive, diagnostic, aptitude, achievement), and/or observation of public behavior, UNLESS: information obtained is recorded in such a manner that human subjects can be identified; AND any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects’ financial standing, employability, or reputation. |
|  | **Exemption III (members of public office)**Same types of possible research as Exemption II, except that the human subjects are elected or appointed officials or candidates for public office and that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.  |
|  | **Exemption IV (secondary data)**Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens of human subjects, IF these sources are publicly available OR if the information is recorded by the investigator in such a way that subjects cannot be identified, directly or through identifiers linked to the subjects.  |
|  | **Exemption V (program evaluations)**Research and demonstrations projects which are conducted by or subject to the approval of department or agency heads, and which are deigned to study, evaluate, or otherwise examine: public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in methods or levels or payment for benefits or services under those programs. |
|  | **Exemption VI (taste and food quality per FDA)**Taste and food quality evaluation and consumer acceptance studies, IF: wholesome foods without additives are consumed, OR a good is consumed that contains an ingredient, agricultural chemical, or environmental contaminant at or below the level and for a use found to be safe by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspective Service of the U.S. Department of Agriculture.  |

1. **DOCUMENT ATTACHMENTS**

**Check (X) all possible items that apply to your project and attach each checked item to your proposal.**

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|  | **Letters, emails, flyers, advertisements etc. that will be distributed to recruit subject participation**  |
|  | **Questionnaires, surveys, or other data-gathering forms**  |
|  | **Consent Form(s) – See Implied and Informed Consent Form Templates on UD IRB website**  |
|  | **Copy of approved proposal or prospectus for thesis or dissertation**  |
|  | **If research has been submitted for grant funding, copy of that proposal, approval, and/or award letter**  |
|  | **Other** (specify)**:**  |

**Continued on next page…**

**NOTE FOR STUDENT PROJECTS: any cover letters, consent forms, and/or questionnaires that students give to research participants must include the following statement:**

*This survey (or project, etc.) is being conducted in partial fulfillment of the course requirements for (course title), taught by (instructor name), at the University of Dubuque. This course is in compliance with the course certification requirements of UD’s Institutional Review Board for the Protection of Human Subjects.*

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|  | **Research Protocols** (if you have NOT checked boxes in BOTH sections of **Part II**, provide the outlined items below as an additional document attachment) |

**Methodology**

* 1. Describe who the project research subjects will be and how they will be solicited, recruited, or contacted.
	2. State how much time will be required of each subject.
	3. Describe procedures, methods, and strategies to which subjects will be subjected. Indicate what data, measures, and/or observations will be collected and used in the project, including any plans to audio or video record human subjects.
	4. Identify if and how participants will be debriefed on the project or study results.

**Voluntary Participation**

1. Specify the steps that will be taken to insure that each individual’s participation is voluntary.
2. State what, if any, inducements or incentives will be offered for subject participation.

**Confidentiality of Data and Privacy Protection**

1. State what identifying information, if any, will be collected (e.g. cohort databases that include SSN# data on individuals, surveys or interviews by name or student number, etc.).
2. Describe the methods to be used to safeguard the privacy of your subjects and ensure the confidentiality of data obtained, including the storage and destruction of data, including that of computer, print, audio and/or video materials.
3. Identify plans to share this data with any intended audiences (such as in a performance report for funding source, conference presentations, published articles or reports, etc.).

 **Risks to Participants**

1. Describe any potential risks to participating individuals – physical, emotional, spiritual, psychological, social, legal, professional, or other.
2. Include all known and anticipated risks to the participants such as side effects, risks of placebo treatments, etc.
3. If research proposes substantial risk to human participants, list emergency backup procedures in place and made available to subjects, such as medical or counseling interventions.

**Benefits for Participants**

1. Describe the benefits and/or any compensation that the participating individuals can expect.
2. Describe the gains in knowledge that may result from the project or study.
3. **CERTIFICATION AND SIGNATURES**

In making this application, I certify that I:

1. Have reviewed all information on the University of Dubuque Institutional Review Board for Human Subjects’ Protection on the Campus Portal at [ww.dbq.edu](http://www.dbq.edu/).
2. Intend to comply with the University of Dubuque IRB policies.
3. Agree to comply with federal, state, and local laws regarding the protection of human participants in research.
4. Will submit any future changes to the research project for IRB review and approval prior to implementation.
5. Agree any adverse events that occur in the course of the study will be promptly reported to the IRB in writing.
6. Understand that records of the participants will be kept for at least three (3) years after the completion of the research for the purpose of IRB inquiries.
7. May begin research when the IRB gives notice of its approval.

**E-Signature of Principal Investigator:  Date: **

Approval by Faculty Advisor (e.g., dissertation, thesis, student study or project involving human subjects’ research):

1. I confirm the accuracy of this application and accept responsibility for the conduct of this research.
2. I will review relevant policies regarding the ethical treatment of human subjects before students begin research.
3. I will exercise reasonable and customary supervision in an attempt to ensure student compliance with the policies for the protection of human subjects at the University of Dubuque.

**E-Signature of Faculty Advisor:  Date: **

1. **CERTIFICATION AND SIGNATURES (continued)**

**FOR IRB COMMITTEE USE ONLY**

**This application has been reviewed by the University of Dubuque IRB and based on the requirements for the protection of human subjects is…**

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|  | **Approved as Exempt IRB Review – Course Certified**  |
|  | **Approved as Exempt IRB Review** |
|  | **Approved after Expedited IRB Review (committee chair and/or appropriate committee member)**  |
|  | **Requiring Full Review by IRB Committee**  |
|  | **Approved after Full Review by IRB Committee** |
|  | **Conditions that must be met for the above:** |
|  | **In need of further information to reach a decision:** |
|  | **Not approved, based on:** |

**E-Signature of IRB Chair:  Date: **

*Copies of this form are to be kept on file by the IRB Committee and Principal Investigator*