Instructions

Please read and complete all sections of this application. Sections cannot be left blank, if you believe something is not applicable to your specific application please clearly mark NA. Incomplete forms will be returned to applicants without review.
If you have any questions please contact your college subcommittee chair (http://www.weber.edu/IRB/application_form.html)

Researcher Agreement and Signatures
The research study involves the use of human subjects. I understand the university's policy concerning research involving human subjects and by submitting this application I agree to:

- ☐ Obtain voluntary and informed consent of subjects who are to participate in this project.
- ☐ Report to the IRB any unanticipated effects on subjects which become apparent during the course of, or as result of, the experimentation and the actions taken.
- ☐ Cooperate with members of the committee charged with continuing review of this project.
- ☐ Obtain prior approval from the committee before amending or altering the scope of the project or implementing changes in the approved consent document.
- ☐ Maintain the documentation of consent forms and progress reports as required by institutional policy for three years.
- ☐ Safeguard the confidentiality of research subjects and the data collected when the approved level of research requires it.

Checklist of Potential Additional Documents:

-Consent documents
-Assent and parental permission documents if participants are under 18
-Copies of CITI training certificates for all study personnel
-All instrument, questionnaires, surveys, interview questions, discussion questions
-Recruiting Materials (including scripts, flyers/posters, letters, screen shots of online recruiting materials, etc.)
-Request for Modification of Consent form, please fill out WSU IRB Amendment form found here
-Faculty Sponsor/Mentor Agreement Form (If student lead research)
-Letters of support from sponsoring institutions/organizations, if applicable
-Photographic/Video Release, if applicable

Signature of the Principal Investigator Date

Department Chair/Supervisor Name
Department Chair Supervisor Signature Date
(NOTE: As Required by department or University division)

WEBER STATE UNIVERSITY
Institutional Review Board

1. Application Information

1.1 Title

1.2 Principal Investigator

1.3 Research Personnel- Please list all personnel and their role (e.g., student researcher, faculty advisor etc.) in the project who will interact with human subjects or have access to data.

1.4 Research Location(s)

1.5 Research Duration (Please list tentative start and end dates) NOTE: Research cannot begin until approval is received.

2. Research Proposal

2.1 Research Summary and Justification (This section should provide a detailed summary that includes background, justification, and hypothesis for the proposed research. Please limit this section to 1 page, citations should be included as a separate Appendix).

2.2 Research Categorization
Research maybe considered exempt if one or more of the criteria listed below apply.
Do you believe the research in this application meets the criteria for exemption?

If yes, please select all categories that you believe apply, If no, skip to section 3.

NOTE: Pseudonyms/randomized numbers in which characteristics are linked to a particular individual may not be sufficient given study design. For more information, NIST provides an overview on de-identification see http://nvlpubs.nist.gov/nistpubs/ir/2015/NIST.IR.8053.pdf

☐ Yes	**Instruction, Curricula, and Classroom Management Research-** educational research in educational settings that involves **ALL** of the following: 1. Research on regular or special instructional strategies; 2. Research that does not likely adversely impact i) students' opportunities to learn or ii) impact teachers' ability to provide instruction or assessment; and 3. Research on instructional techniques, strategies, curricula, or classroom management methods. **Note: This does not include: test, or survey/interview/observational research, see below.**
☐ Yes	**Test Research**- research using educational tests (cognitive, diagnostic, aptitude or achievement) **AND** includes **ONE** of the following: 1. Researcher records the information in such a manner that the identity of the subjects cannot be readily ascertained directly or indirectly 2. Disclosures of subjects' responses would not place subjects at risk of any of the following: civil liability, criminal liability, financial damage, damage to employability, or damage to reputation 3. Researcher employs Weber State University IRB authorized data management procedures in compliance with the guidance from HHS on confidentiality of data.
☐ Yes	**Adult Survey, Interview and Observational Research**-research on subjects who are 18 or older using surveys, interviews, or observations of public behavior; and includes **ONE** of the following: 1. Researcher records the information in such a manner that the identity of the subjects cannot be readily ascertained directly or indirectly. 2. Disclosures of subjects' responses would not place subjects at risk of any of the following: civil liability, criminal liability, financial damage, damage to employability, or damage to reputation; or 3. Researcher employs Weber State University IRB authorized data management procedures in compliance with the guidance from HHS on confidentiality of data.
☐ Yes	**Minor Educational Tests and Observational Research**-research on subjects below the age of 18 involving observations of public behavior and educational tests when investigators do not participate in the activities being observed; and includes ONE of the following: 1. Researcher records the information in such a manner that the identity of the subjects cannot be readily ascertained directly or indirectly; or 2. Disclosures of subjects' responses would not place subjects at risk of any of the following: civil liability, criminal liability, financial damage, damage to employability, or damage to reputation.
☐ Yes	**Adult Research Involving Benign Behavioral Interventions**- research on subjects who are 18 or older that includes:

	1. Research that is brief in duration, painless, harmless, not physically invasive, not likely to have adverse impacts or not likely to be offensive, embarrassing to research subjects, and instances involving deception, the research subjects are apprised that they may be unware or misled regarding the nature of the research; 2. Research that includes data collection through verbal or written responses; 3. Research in which the research participant prospectively agrees to the invention and data collection; and **ONE** of the following: ▪ Researcher records the information in such a manner that the identity of the subjects cannot be readily ascertained directly or indirectly ▪ Disclosures of subjects' responses would not place subjects at risk of any of the following: civil liability, criminal liability, financial damage, damage to employability, or damage to reputation; or ▪ Researcher employs Weber State University IRB authorized data management procedures in compliance with the guidance from HHS on confidentiality of data in accordance with 45 CFR 46.111(a)(7).
☐ Yes	**Research on Existing Data With No Consent Required**-secondary research not requiring consent that involves identifiable private information or identifiable biospecimens that includes at least **ONE** of the following: 1. Publicly available; 2. Research does not contact subjects or re-identify subjects. Researcher records the information in such a manner that the identity of the subjects cannot be readily ascertained directly or indirectly 3. Research involves identifiable health information regulated by HIPPA for "health care operations" (e.g. improvement activities etc.) or "research" as defined in 45 CFR 164.501 or "public health activities and purposes" (e.g. disclosure to CDC etc.); and 4. Research is conducted on behalf of federal department or agency using government information which is controlled by the E-Government Act of 2002 and is maintained on systems subject to the Privacy Act of 1974 and, if applicable, the information was gathered subject to the Paperwork Reduction Act of 1995.
☐ Yes	**Federally Funded Research on Public Benefit Programs**- research funded and approved by federal agencies and departments that study, evaluate, improve or otherwise examine federal benefit programs which will be published on a list in accordance with 45 CFR 46.104(5)(i) prior to the commencement of the research.
☐ Yes	**Taste and Food Quality Research** –research involving taste and quality of food which does not have additives or has ingredients/chemicals/contaminants at levels approved by the Food and Drug Administration, Environmental Protection Agency or Food Safety and Inspection Service.
☐ Yes	**Storage/Maintenance of Secondary Research Requiring Consent**- involves the storage and maintenance of secondary research of identifiable private information or identifiable biospecimens in which IRB will conduct the limited IRB review required in 45 CFR 46.111(a)(8).
☐ Yes	**Secondary Research Requiring Consent**- research involving identifiable private information or identifiable biospecimens for secondary research including **each** of the following: 1. Broad consent in accordance with 45 CFR 46.116(a)(1) was obtained; 2. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR 46.117; 3. Researcher employs Weber State University IRB authorized data management procedures in compliance with the guidance from HHS on confidentiality of data in accordance with 45 CFR 46.111(a)(7) ; 4. IRB will make a determination whether the research is within the scope of the broad consent

3. Research Population

3.1 Number of Subjects and a justification for the number of subjects to be enrolled (e.g., power/sample size analysis, citation of comparable studies from the literature).

3.2 Age range of Subjects:

3.3 Vulnerable Populations (check all that apply)

☐ Individuals under the age of 18	☐ Institutionalized
☐ Pregnant Women	☐ Students Enrolled in Your Class(es)
☐ Prisoners	☐ Individuals with Cognitive Impairments
☐ Economically Disadvantaged Persons	☐ Educationally Disadvantaged Persons

*If the proposed research will include a vulnerable population, as identified above, please provide justification for their inclusion.

3.4 Please briefly describe your inclusion and exclusion criteria.

4. Subject Recruitment, Consent and Compensation

4.1 Which of the following tools will be used to recruit subjects? (Check all that apply). Attach a copy of all recruitment materials (i.e., scripts, flyers, screenshots of online material, etc.) with the application.

☐ Posted/Distributed Flyer	☐ Third party/Non-Study Personnel/ Professional recruiters
☐ Classroom Announcement	☐ Website/Social Media/Online
☐ Email to Subjects	☐ Other:

4.2 Please briefly describe the *recruitment* procedures.

4.3 Please briefly describe the *process to obtain their consent*. Please be sure to attach all of the necessary consent forms with the application

4.3.1 Will the proposed research likely involve subjects or parents/guardians of subjects who are not fluent in English?

If yes, please submit an English version of the consent form AND a version of the consent form translated into the appropriate language(s) as attached documents.

4.3.2 Will the proposed research likely involve subjects or parents/guardians of subjects who are not literate?

If yes, please describe how you will secure lawful consent from these participants?

4.4 Subject Compensation

4.4.1 Will subjects be compensated for participation? If yes, please describe the form of compensation (i.e., cash, check, gift certificate, voucher, 1099, etc.)

4.4.2 If compensation is monetary please provide the amount of compensation.

4.4.3 Please provide a brief justification for the form and amount of compensation provided to subjects, and how the amount of compensation does not unduly influence participation in research.

4.4.4 Please describe when and how compensation will be provided to subjects.

4.4.5 Will compensation be prorated?

If yes, please describe how proration will occur.

4.4.6 For research involving students, will compensation be provided in the form of class credit to students that choose to participate?

If yes, describe how students who choose not to participate in the research may earn class credit. The alternative method to earn class credit should be comparable in time and effort required for research subjects to complete study tasks.

5. Research Methods

5.1 Write a complete and thorough description of the procedures subjects in the proposed research will take part in. This description should encompass the experimental course of a subject from their entry into the study to their completion of the study.

5.2 Many studies use multiple instruments/questionnaires/surveys as part of the research methodology. If applicable to the proposed research, list each instrument/questionnaire/survey that will be administered to subjects and provide a rationale for the inclusion of each one.

5.3 Data Analysis: Whether quantitative or qualitative, please provide a detailed description of the research design/statistical design and data analysis plan for the proposed research.

5.4 Please provide the following: i) how many times human subjects will perform research activities; ii) how long each visit will take; iii) the total time requirement for a subject to complete the proposed research?

5.5 Will the research involve deception or less than full disclosure?

If yes, please justify the need for deception in the proposed research.

5.6 Does the research involve audio/video recording or photography of subjects? If yes, please describe how and in what situations the recordings/images will be used. If applicable, attach the video/photographic release form

5.7 Will subjects be followed after completion of the proposed research? If yes please explain.

6. Risk, Data Management, and Confidentiality

The following questions address your efforts to balance benefits and risk, and maintain subject confidentiality in the proposed research.

6.1 Risk: Generally, risk assessment in research considers the harm, trauma, discomfort, stress, or any other undesirable or untoward consequence of being a research subject whether anticipated or unexpected. Risk may take the following forms: physical, psychological, emotional, financial, and/or social. This list is representative but not comprehensive. Please consider the following questions based on the experiences that subjects might encounter through participation in the proposed research.

6.1.1 Whether great or small, please describe the potential risks to subjects that participate in the proposed research.

6.1.2 What steps will be taken by the investigator to reduce the aforementioned risks?

6.2 Benefits

6.2.1 Please describe any benefits that research subjects will receive as a direct result of their participation in the proposed research. (Note: compensation is not considered a benefit)

6.2.2 Please describe how this research may provide benefit to scientific knowledge, a specific discipline, and/or society in general.

6.3 Protecting hard copy data may involve de-identification of data (see:NISTIR-8053) and secured storage locations and conditions (see: Weber State University PPM 10-1). Describe what type of hard copy data will be generated by the proposed research (i.e., notes, audio/video tapes, questionnaires, etc.). Where will this hard copy data be stored and how will it be protected?

6.4 Protecting electronic data may involve a secure network, password access, and data de-identification/ encryption (see: Weber State University PPM 10-1) Describe what type of electronic data will be generated by the proposed research (i.e., computer files/ spreadsheets, questionnaires, images, video, audio/mp3 files, etc.).Where will this electronic data be stored and how will it be protected

6.5 If the data has identifiable subject information associated with it, please describe how the data will be de- identified.

6.6 Will the research require accessing student educational records? If yes, please describe the procedures you will employ to access the information. Specify the information you will request

6.7 How long will data from this study be maintained by the principal investigator?

6.8 Will raw data be made available to anyone other than the principal investigator and the immediate study personnel? If yes, describe the rationale and procedure for sharing study data. Include a description of what will be shared and with whom. Specify the protections in place to transfer the data.