**Exempt Study Review Form**

**Principal Investigator (PI) Information:**

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| Name of PI: | School/Department: |
| Email Address: | Phone Number: |
| PI Status:  Faculty  Adjunct Faculty  Graduate Student  Undergraduate Student  Staff  Other (Specify:      ) | |
| Protection of Human Subjects Training:  Date of Completion:  Additional Training, Date of Completion:  Please include proof of training with this application. Completion Date must be within past three years. Please note that anyone that will be interacting with human subjects in addition to the PI should have completed training. | |

**For Sponsored Projects (required when the PI is a student):**

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| Supervising Faculty: | School/Department: |
| Email Address: | Phone Number: |

**Project Information:**

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| Project Title: |
| Type of Project:  Individual Research Project  Class Project  Thesis/Dissertation  Course Exemption (Course Section & Title:       Semester:      )  Other:  Please note that only faculty teaching courses may apply for course exemption. |

**Does this research involve minors?**  Yes  No

Research with children is exempt for categories 1, 4, 5, 6, 7, and 8 if the conditions of the exemption are met. Observation of the public behavior of children under Category 2 is allowed only if the researcher does not take part in the activities being observed. Surveying and interview procedures (category 2), as well as research under category 3 conducted with children may not be exempt.

**Does this research involve other vulnerable populations (i.e., prisoners, individuals with impaired decision-making ability, etc.)?**  Yes  No

**Please review the eight [8] categories of exemption listed below and check all that apply to your research.**

1. Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices, that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

1. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
2. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
3. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7)

3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

1. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
2. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
3. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

For the purpose of this provision, benign behavioral interventions are 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. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

* 1. The identifiable private information or identifiable biospecimens are publicly available;
  2. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
  3. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or
  4. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

1. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient 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 (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service of the U.S. Department of Agriculture (USDA).

7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by § 46.111(a)(8).

8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

1. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § 46.116(a)(1) through (4), (a)(6), and (d);
2. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § 46.117;
3. An IRB conducts a limited IRB review and makes the determination required by § 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and
4. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

**Summary**: Please provide a brief summary of the objectives and significance of this research.

**Participants:** Please briefly describe your participants. Include an estimated total number of participants, a description of the population they will be recruited from, and a description of how they will be recruited. Please submit all recruitment materials with this application.

**Does your study involve transferring identifiable information and/or biospecimens to and/or from a European Country (e.g., an online survey open to participants in Europe)**

Yes  No

**Are you requesting a waiver or alteration of informed consent?**  Yes  No

**If yes, please justify why informed consent should be waived/altered:**

**If no, how will you be documenting informed consent? Please also describe your consent process.**

**If you are working with minors, will you be obtaining assent?**  Yes  No  N/A

**If yes, please describe your assent process?**

**If no, please justify why you are not obtaining assent.**

**Will you be obtaining broad consent?**  Yes  No

Please submit all consent/assent documents with this application.

**Will participants be compensated for participation?**  Yes  No

**If yes, how?**

**Methodology:** Please provide a brief but complete description of how the research will be conducted, including what participants will be told and what they will be doing. Please submit all questionnaires, surveys, or other measures with this application.

**Confidentiality:** Please provide a brief but complete description of how confidentiality will be maintained before, during, and after data collection

**Assurances:**

I, the investigator (and if applicable, the faculty sponsor), certify that to the best of my knowledge the research described above qualifies for exemption under 45 CFR§46-104. I agree that any changes to the project will be submitted to the Institutional Review Board before they are implemented, and that any adverse events will be reported in a timely manner. I also recognize that the Institutional Review Board is only responsible for ensuring the safety and integrity of human participants. I recognize that I am responsible for ensuring this research complies with the mission statement of the University.

The PI’s signature (and that of the faculty sponsor, if applicable) is required before this application can be processed (electronic signatures are acceptable). Send this application and all supporting documents to [irb@caldwell.edu](mailto:irb@caldwell.edu). Please note that this document and any others requiring IRB stamps must be in doc/docx format so that the electronic stamp may be applied. Any other formats will be returned.

**Principal Investigator** **Date**

**Faculty Sponsor Date**

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| **This Section is for IRB Use Only**  Exemptunder 45 CFR§46.101(b)  Yes  No  Notes:  Reviewed by:  Stamp: |