THE COLLEGE of IDAHO

IRB Office
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**IRB Protocol Cover Sheet**

| | | | |
|---|---|---|---|
| **Project Title**: | | | |
| **Principal Investigator**:<br>(print) (signature) | | | |
| **Email Address**: **Campus Box**: | | | |
| **Mailing Address**:<br>*(If no campus box)* *Street* | | | |
| *City* *State* *ZIP* | | | |
| **Additional Investigators**: | | | |
| **Faculty Sponsor**<br>(Signature required before review) | | | |
| **Level of Review Requested:**<br>(Please type an X in front of appropriate level) | Exempt | Expedited | Full |
| **Date Submitted**: **Anticipated End Date**: | | | |

*January 2021*

# I. PROJECT TEAM & HUMAN RESEARCH EDUCATION.

- List all individuals who will: (1) obtain data about research participants through intervention or interaction with them; or (2) obtain or access identifiable private information or identifiable specimens about the participants of the research – even if they do not directly interact with them. These individuals are considered "engaged" in the research.
- **The Faculty Sponsor is always engaged in the research and must be listed as a project team member.**

**All members of the project team must complete an education program for the protection of human research participants prior to conducting this, or any other, research involving human participants.**

| **Name**<br><br>*Please use full legal name* | **Title/Institution/Department**<br><br>*For example: Undergraduate Student/C of I/Sociology* | **Ethics Training**<br><br>*Granting organization (NIH or CITI?), certification #, date completed*<br><br>**Note: must have been completed within the past 5 years** |
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# II. Description of Project

Provide a **detailed** description of your project either in the box below or **attach** a written protocol. Please include the following: research question, rationale for your study, recruitment procedures, description of subjects (age, students, etc), mechanism for obtaining consent/assent, protocol, mechanisms to maintain confidentiality or anonymity, and how data will be stored and/or destroyed. **Your application will not be reviewed without this document.**

## III. FUNDING INFORMATION

**How is this project funded?**

[ ] No funding

[ ] PI/PD department and/or discretionary funds

[ ] Industry: Sponsor Name _____

[ ] Grant

[ ] Awarded [ ] Pending

Source _____

## IV. Determining Category of Review

## Part A: Is your research exempt from IRB oversight?

Please check any boxes that apply to your research project. In the text box at the end of this section, explain why you believe your project qualifies for exemption.

☐ **Category 1 (Educational research):**

Research, conducted in established or commonly accepted educational settings, which 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 most 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.

☐ **Category 2 (Anonymous/non-sensitive surveys, interviews, etc.):**

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:

(i) 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;

(ii) 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

(iii) 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.

☐ **Category 3 (Benign behavioral interventions):**

(i) 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:

(A) 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;

(B) 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

(C) 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.

(ii) 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.

(iii) 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.

☐ **Category 4 (Secondary research on existing data or specimens):**

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:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) 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;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information.

(iv) The research is conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology.

☐ **Category 5 (Research conducted by federal agencies):**

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.

☐ **Category 6 (Food acceptance studies):**

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 or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

☐ **Category 7 (Setup of a data and specimen bank):**

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.

☐ **Category 8 (Banked data and specimen banking with broad consent):**

Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if broad consent or waiver was obtain in accordance with OHRP guidelines.

**Explain why you believe your proposal is Exempt from IRB Oversight.**

**The Following can NOT be exempt**

[] My research does not involve any of the following:

- research involving prisoners after incarceration;
- surveys or interviews of children;
- observation of children when the investigator will interact with them;
- data obtained from adults through administration of educational tests, survey procedures, interview procedures, or by observation of public behavior IF the information is recorded in such a way that the identity of individuals can be identified either directly or through identifiers linked to the individuals AND disclosure of participants' responses could reasonably place them at risk of criminal or civil liability or be damaging to an individual's financial standing, employability, or reputation;
- observation of behavior that takes place in settings in which participants have a reasonable expectation of privacy;
- research techniques which expose participants to discomfort or harassment beyond levels encountered in daily life (i.e., greater than minimal risk);
- deception of research participants unless prospective authorization has occurred; and
- research that involves a test article regulated by the FDA unless the research meets the criteria for exemption.

**If you checked at least one box for Categories 1-8 AND you checked the final box, then your research might be exempt from IRB oversight. You may skip Part B. Please fill out the remaining items, beginning in section V, and submit to the IRB. Please do not begin your research until the IRB officially confirms the exempt status of this project.**

**If you did not check any boxes in this section, please proceed to Part B to determine if your project qualifies for expedited review.**

## Part B: Does your project qualify for Expedited Review?

**Some non-exempted research qualifies for expedited review. Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.**

Some research projects qualify for an expedited review process. These research projects must meet the definition of minimal risk and fall into one of the following categories. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

**DOES YOUR RESEARCH MEET THE DEFINITION OF MINIMAL RISK?**

___Yes ___No

If no, skip to Section V; your proposal will require full board review.

If yes, please select the appropriate category below. Please check any boxes below that describe your research. If your research does not fall into any of these categories, then it must undergo a full review (review by entire IRB at a scheduled meeting).

[] **Category1**. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application is not required.

(b) Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

[] **Category 2**. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

[] **Category 3**. Prospective collection of biological specimens for research purposes by noninvasive means.

[] **Category 4**. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

[] **Category 5**. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes, such as medical treatment or diagnosis.

[] **Category 6**. Collection of data from voice, video, digital, or image recordings made for research purposes.

[] **Category 7**. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

[] **Category 8**. Continuing review of research that is greater than minimal risk and has been initially reviewed and approved by the convened full-board IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

## V. PERFORMANCE SITES. Check ALL locations where research procedures will take place

[ ] The College of Idaho campus

[ ] Online research (such as online surveys)

[ ] Another college/university, K-12 school, school district, or organization (such as the YMCA, a church, etc.) **You must have written permission to conduct research at this site. Please attach a copy.**

[ ] Other. Indicate geographic location (e.g., state, country, province, village) in the box below.

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If you are conducting research in another country you must follow regulations of that country.

**[ ] I understand that it is my responsibility to obtain any additional approvals, which may be required to conduct research in this country.** *(The IRB may ask for written documentation.)*

## VI. POPULATIONS INCLUDED IN THIS STUDY <u>Check ALL that apply.</u>

**><u>Adults</u>.** Note: Legal age of adulthood varies by location (i.e., state, country). In Idaho, the legal age of adulthood is 18, but it differs in other states and countries. If you will be doing any research outside the state of Idaho, please check the legal age.

[ ] Adult population

Will any of these adults be C of I students? [ ] Yes [ ] No

>>If yes, do you plan to use the Psychology Dept Undergraduate Student Pool? **Note that you must check the student box below for special populations.**

[ ] Yes [ ] No *(If yes, you must comply with Subject Pool policies. Contact Professor Cara Laney claney@collegeofidaho.edu with questions.)*

**><u>Children</u>.** As defined according to the laws in the jurisdiction in which the research will be conducted. (See note re. legal age of adulthood above.) ***Federal regulations at <u>45 CFR 46 Subpart D</u> apply when children are research participants***

[ ] Child population. Age range: _____

**>Special Populations.** If you are working with any of these special populations, please fill out additional forms as indicated. If no special form is required, be sure to explain in your narrative description (Section II) how you will minimize risk.

[ ] Individuals with impaired decision-making capacity. ***Special protections are required. Please complete & attach Research on Individuals with Impaired Decision-Making Capacity .***

[ ] Economically or educationally disadvantaged. ***Voluntary participation must be assured. Recruitment and consent must be free from coercion or undue influence.***

[ ] Employees in their work place. ***Voluntary participation must be assured. Recruitment and consent must be free from coercion or undue influence.***

[ ] Pregnant Women ***If your research does not qualify as exempt, please complete & attach Behavioral form for Research Involving Pregnant Women.***

[ ] Prisoners – ***IF SUBJECT IS ALREADY INCARCERATED,*** **RESEARCH MUST BE REVIEWED BY A FULL BOARD COMMITTEE.**

[ ] Severely physically ill. ***Recruitment and consent must be free from coercion or undue influence.***

[ ] Students. ***Recruitment and consent must be free from coercion or undue influence.***

[ ] Third parties. A third party is an individual about whom an investigator obtains information from research participants but who themselves have no interaction with the researcher and/or individuals from whom an investigator obtains information about the research participant ("informants").

[ ] Other: _____

## VII. RECRUITMENT TECHNIQUES. Check ALL that apply.

[ ] Not applicable. Research procedures involve only collection of materials (data, documents, records).

[ ] Psychology Dept. Undergraduate Student Pool

[ ] Advertisements, flyers **(attach sample)**.

[ ] Educational Setting: Letter to potential participant/ legal guardians in one's own classroom

[ ] Other, please describe:

## VIII. NUMBER OF PARTICIPANTS

How many participants do you anticipate?_____

Will anyone be excluded from your study? ___Yes ___No

If yes, please explain why.

## IX. PROTECTION AND PRIVACY OF RESEARCH SUBJECTS

### a. DURING RECRUITING AND DATA COLLECTION

How will you protect the privacy of research participants? (Example: Providing a private meeting place for a survey of victims of child abuse.)

### b. PROTECTION OF DATA COLLECTED: ANONONYMITY OR CONFIDENTIALITY?

"Anonymity" means that no one (not even the researcher) can connect the data with the participant. "Confidentiality" pertains to how you will protect the information provided by participants or that you obtain for research purposes. This includes information that an individual discloses in a relationship of trust and with the expectation that it will not be divulged, without permission, to others in ways that are inconsistent with the understanding of the original disclosure.

**Indicate by checking the appropriate box whether the data will be anonymous or confidential**.

[ ] Anonymous

[ ] Confidential (face-to-face research may be confidential, but not anonymous)

Indicate the steps by which the anonymity or confidentiality of the data will be maintained.

**Indicate how data will be stored.**

1. **Electronic Data.** Check ALL that apply.
   [ ] Secure network

   [ ] Password protected

   [ ] Coded, with key kept separately and secured with safeguards

   [ ] Other. Please describe:

   __ n/a

2. **Hardcopy Data.** Check ALL that apply.
   [ ] Locked suite and/or office

   [ ] Locked file cabinet

   [ ] Coded, with key kept separately and secured with safeguards

   [ ] Other. Please describe:

   __ n/a

## X. COMPENSATION

Will participants receive any compensation or benefit for participation?

[ ] Yes [ ] No

If yes, describe.

## XI. RISKS (Research that is eligible for expedited review must not pose more than minimal risk)

Minimal Risk definition: the probability and magnitude of harm or discomfort anticipated are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Describe any potential risks to participants. Consider psychological, social, legal, and economic harm an individual could reasonably experience as a result of participating in this research, as well as physical risks. **If "no known risks" exist, you may use that statement as your response.** Describe procedures that will be used to minimize those risks.

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Is death a possible risk from this study?

_yes
_no

## XII. DECEPTION

Will deception be used?

[ ]Yes [ ] No

If yes, describe the nature of the deception and a justification for its use. **Note: Deception is typically considered to involve greater than minimal risk to participants, unless the deception involves ONLY the omission of the true purpose of the research (i.e. to avoid demand characteristics) or other non-harmful omissions (e.g., a surprise memory test at the end of an experiment).**

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## XIII. ADDITIONAL INFORMATION REGARDING METHODS AND PROCEDURES

**A.** Will you be conducting interviews?
[ ] No

[ ] Yes. If yes, **attach a list of questions you will ask**.

**B.** Will you be using surveys or questionnaires?
[ ] No
[ ] Yes. If yes, list all surveys or questionnaires in the box below. **Attach a copy of each survey or questionnaire.**

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**C.** Will you be conducting a behavioral experiment?
[ ] Yes [ ] No
If yes, will you be using
[ ] Non-emotionally evocative stimuli. **Attach a representative sample of each type of stimulus you will use.**

[ ] Emotionally evocative stimuli. **Attach a complete set of <u>all</u> stimuli that may be used.**

**D.** Does this research involve the use of audiotapes, videotapes, or photographs?
[ ] Yes [ ] No
If yes, please be sure to include this in your consent form.

**E.** Will you be drawing blood? [ ] No [ ] Yes
If yes, please see the Expedited Category 2 guidelines
Please describe the age and weights of individuals from whom blood will be taken, the number of draws per week and the total amount of blood drawn

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## *XIV.* INFORMED CONSENT PROCESS

**Federal regulations require that participants are informed about the research in which they are going to be involved. Ideally, this is a written consent form that is signed by the adult participant or parent/guardian of a minor.**

**A. Check all that apply:**

**[ ] Standard Written Consent** (Please see example form for guidance**) Attach consent form**

**[ ] Oral Consent** (Attach script and justify in the box below)

**[ ] Altered written consent** (If any required elements are omitted you must justify in the box below) **Attach consent form**

**[ ] Implied consent as in the case of online consent forms in which a signature is not obtained** (Considered a waiver of consent—justify below) **Attach written consent form, if applicable**

**[ ] Broad Consent** (For use when gathering identifiable samples that will be kept for future research)

**[ ] Complete waiver of consent**. Provide a justification for your request below.

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**B. Describe when, where and how consent will be obtained.**

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**C.** Will participants be offered an alternative activity? (Note: This is important in situations such as a classroom setting where those who choose not to participate may feel uncomfortable without an alternative activity.)

[ ] yes
[ ] no

# Checklist for New Submissions

Note that your proposal will be returned if the required items are not included

[ ] This form with all relevant questions answered, including a signature.

[ ] All necessary additional forms (e.g. must have an additional form if you are working with minors)

[ ] Interview questions or surveys, if applicable

[ ] Recruiting materials/advertisements, if applicable

[ ] Consent Form

[ ] Assent Form (written or script for oral) if working with minors

[ ] Letter of permission if doing the research at another school, organization or business. For example, if doing your research at a public school, you will need a letter from the principal or other appropriate administrator.