**Lander University**

**IRB Research Application**

**(This application covers Exempt, Expedited, and Full Committee review categories.)**

To be completed by IRB Representative

Research Category: 1 2 3 4 5 6 7 8 9

Approved by: Approval Date:

IRB Chair or Designee Expiration Date:

*Applicants must be Lander University faculty or staff. All student (undergraduate and graduate) research projects must be supervised by a faculty or staff member. All individuals conducting research with human participants must have a current CITI certificate documenting completion of human research protections training, which can be obtained free through* [www.citiprogram.org](http://www.citiprogram.org). *Note: the Social and Behavioral Research - Basic Course is the minimum certification required; the IRB may require additional training and certification if deemed relevant to the project parameters.*

**Principal Investigator (PI):** Department:

E-mail: Phone:

Campus address:

University status: Faculty Staff

CITI expiration date:

**Research Personnel:** *If other individuals will assist with recruiting, obtaining informed consent, data collection or data collection list their names, University status, and CITI expiration date below.*

Co-PI/Research Assistant: Department:

University status: Faculty Staff Student

CITI expiration date:

Is Co-PI a graduate student? No Yes

Co-PI/Research Assistant: Department:

University status: Faculty Staff Student

CITI expiration date:

Co-PI/Research Assistant: Department:

University status: Faculty Staff Student

CITI expiration date:

Co-PI/Research Assistant: Department:

University status: Faculty Staff Student

CITI expiration date:

Co-PI/Research Assistant: Department:

University status: Faculty Staff Student

CITI expiration date:

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**Research Review Categories**

There are three levels of review covered by this application: 1) Exempt, 2) Expedited, and 3) Full Committee.

Federal definition of research requiring IRB review and oversight: **a systematic investigation**, including research development, testing, and evaluation, designed to develop or contribute to **generalizable knowledge** (see CFR 46.101(l)(1-4) for exclusions).

**Instructions: Select one or more of the categories below that appears to be applicable to your research and provide the information requested for each category selected.**

**Category 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 educator 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.

1. Are the research activities a part of the normal class activities? No Yes If NO, describe how the activities will not adversely impact student students’ opportunity to learn the required educational content:
2. Does the project involve a team member who is responsible for evaluating the performance of the instructor(s)? No Yes If YES, describe how the activities will not adversely impact the assessment of the instructor(s) providing instruction:
3. Will the class instructor(s) be evaluated on the performance of the research activities? No Yes If YES, describe how the activities will not adversely impact the assessment of the instructor(s) providing instruction:

**Category 1 may be applied to research involving minors.**

**Category 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 as least one of the following criteria is met:

Check all that may apply:

The information obtained is recorded in such a manner that the **identity of the human subjects cannot readily be ascertained**, directly or through identifiers linked to the subjects. (Criterion may be applied to research involving minors.)

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. (Criterion may be applied to research involving minors.)

The information obtained is recorded in a manner that the **identity of the human subjects can be readily be ascertained**, directly or through identifiers linked to the subjects. (Criterion may NOT be applied to research involving minors.)

**Category 2 may NOT include interventions.**

**Observation of public behavior criteria:** observation occurring in public setting where there are no expectations of privacy (ie. public park, concert) and researchers do not interact with participants.

**Category 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.

1. Does the research involve benign behavioral intervention(s) as described below? No Yes If NO, your project **does not meet** the criteria for Exempt review under Category 3. If YES, describe intervention(s) :
2. Does the research involve deceiving the participants of the nature or purposes of the research? No Yes If YES, see guidance on Research Involving Deception of Concealment AND attach the debriefing form for review.
3. Will you notify the participants in the informed consent document that the research involves an intervention and/or deception of the nature or purposes of the research (you do not have to describe the details of the intervention or deception, just that the research involves an intervention and/or deception of the nature or purposes of the research)? No Yes If NO, your project **does not meet** the criteria for Exempt review under Category 3.
4. Check all that may apply:

The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily be ascertained, directly or through identifiers linked to the subjects.

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.

The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily be ascertained, directly or through identifiers linked to the subjects.

**Definition:** 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** of the nature or purposes of the research, the **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 3 may NOT be applied to research involving minors.**

**Category 4:** Secondary research for which **consent is not required: Secondary research uses identifiable private information or identifiable biospecimens.**

1. Was the data or biospecimens **initially** collected for non-research purposes or from other research studies that did not required the participants’ informed consent? No Yes If NO, your project **does not meet** the criteria for Exempt review under category 4. Go to Category 8.
2. Check all that may apply:

The identifiable private information or identifiable biospecimens are **publicly available** (either by paying a fee, submitting a request, or available without restrictions).

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.

The research involves only information collection and analysis involving the investigator’s use of **identifiable health information** when that use is regulated under HIPPA (45 CFR parts 160 and 164, subparts A and E), for the purposed 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 at 45 CFR 164.512(b).

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. 552(a), 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.

1. List the data fields and/or describe the biospecimens that will be used:
2. Identify the data holder and/or source of the biospecimens:
3. Is a Data Use Agreement and/or Material Transfer Agreement required for you to access the data and/or biospecimens? No Yes -- provide copy of agreement
4. Describe your management plan for storing and securing the data and/or specimens, including protecting the privacy of participants and maintaining confidentiality of data:

Category 4 may:

* be applied to identifiable private information or identifiable biospecimens collected from minors;
* involve future collection of identifiable private information or identifiable biospecimens if the data or biospecimens are not being collected specifically for your proposed research study.

An Institutional Biosafety Committee (IBC) protocol may be required for secondary research use of biospecimens.

If requesting Exempt review under Category 4 only, then go to question 12 (Conflict of Interest Statement/Financial Disclosure).

**Category 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 included, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants.

**Category 5 may be applied to research involving minors.**

**Category 6:** Taste and food quality evaluation and consumer acceptance studies:

Check all that may apply:

Wholesome foods without additives are consumed.

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

**Category 6 may be applied to research involving minors.**

**Category 7:** Storage or maintenance for secondary research for which broad consent is required:

1. Check all that may apply:

Storage or maintenance of identifiable private information for secondary research.

Storage or maintenance of identifiable biospecimens for secondary research.

1. Was broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens **obtained from participants**? No Yes If NO, your project **does not meet** the criterial for Category 7.
2. Was broad consent obtained in writing or did an IRB waive the documentation for written informed consent? No Yes If NO, your project **does not meet** the criteria for Category 7. If YES, describe the informed consent process:
3. Describe your management plan for storing and securing the data and/or specimens, including protecting the privacy of participants and maintaining confidentiality of data:

Data Use Agreement of Material Transfer Agreement may be required to share the data and/or biospecimens with other researchers.

**Category 7 may be applied to identifiable private information or identifiable biospecimens from minors.**

An Institutional Biosafety Committee (IBC) protocol may be required for secondary research use of biospecimens.

If requesting Exempt review under Category 7 or under Categories 7 and 8 only, then go to question 12 (Conflict of Interest Statement/Financial Disclosure).

**Category 8:** Secondary research for which **broad consent is required:** Research **involving the use of identifiable private information or identifiable biospecimens for secondary research** use.

1. ALL of the following criteria must apply:

Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained;

Documentation of informed consent or waiver of documentation of consent was obtained;

The research to be conducted is within the scope of the broad consent; AND

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.

1. List the data fields and/or describe the biospecimens that will be used:
2. Identify the data holder and/or source of the biospecimens:
3. Is a Data Use Agreement and/or Material Transfer Agreement required for you to access the data and/or biospecimens? No Yes – provide copy of agreement
4. Describe your management plan for storing and securing the data and/or specimens, including protecting the privacy of participants and maintaining confidentiality of data:

**Category 8 may be applied to identifiable private information or identifiable biospecimens collected from minors.**

An Institutional Biosafety Committee (IBC) protocol may be required for secondary research use of biospecimens.

If requesting Exempt review under Category 8 or under Categories 7 and 8 only, then go to question 12 (Conflict of Interest Statement/Financial Disclosure).

**Category 9: Check this category when NONE of the above categories appear to apply to your proposed study.** The IRB Chair will contact you to discuss additional requirements that may apply.

**Description of Research Project**

1. **Project Title:**
2. **Study Purpose and Rationale:** *(Describe the purpose and goals of the research and provide a brief rationale explaining the scientific merit and potential value to participants of the proposed study using plain language. Avoid technical terms, acronyms, or jargon, unless explained)*

**Description:**

1. **Sharing of Results:** *(Describe how research results will be shared, ie. academic publication, evaluation report to sponsor, conference presentation)*

**Description:**

1. **Funding:** Is the research funded? No Yes If YES, answer the below questions.
2. Full name of funding source:
3. Name of PI on award:
4. Was the award processed through InfoEd? No Yes

If YES, enter ten-digit InfoEd proposal number (PPN):

1. Did the IRB office issue a developmental (temporary) approval for this research? No Yes If YES, enter the IRB protocol number:
2. **Research Sites:** Will research activities occur at a non-Lander site? No Yes If YES, site permission may be required. If collecting data at another institution that has an IRB, you may need permission from each participating institution’s IRB office. Contact the Lander IRB to discuss details before submitting your application(s).

**List all applicable non-Lander site locations:**

1. **Study Population:** *(Identify the group(s) specifically targeted for the study. Check all that may apply.)*

Lander students

Lander faculty and/or staff

Adults not affiliated with Lander

Non-English speaking individuals

Individuals with impaired decision-making capacity

Minors, including wards of the state, or any other agency, institution, or entity

Individuals with intellectual disabilities

Individuals economically and/or educationally disadvantaged

Pregnant women

Human fetuses and/or neonates

Prisoners (not eligible for Exempt status)

Department of Defense personnel

Other. Describe:

1. **Research Sample:** How many participants do you anticipate enrolling in the study?
2. **Recruitment Procedures:**
3. Identify how participants will be recruited*. Check all that may apply AND attach a copy of all recruitment documents for review.*

Flyers/Advertisements in public venues

In-person solicitation-describe:

Departmental subject pool-describe:

E-mail notice

Internet advertisement-describe:

Letter mailed to individuals

Other-describe:

1. Are there any inclusion or exclusion criteria for participation? No Yes If YES, describe criteria and screening process to determine eligibility (provide a copy of the screening tool) and briefly explain why the inclusion or exclusion criteria is necessary for your research:
2. **Participant Incentives:**
3. Will participants receive any incentive or compensation for participating in the study? No Yes If YES, answer the questions b-c.
4. Are there any conditions for receiving incentives? No Yes If YES, describe:
5. Check all that may apply and provide the requested information for each incentive checked (all incentives must be listed on informed consent document).

Course/extra credit for students (an equivalent alternative to research participation must be provided and described on the informed consent document)

Indicate the number of credits that will be offered AND if partial credits will be offered:

Gift(s)

Describe gift(s), including the value of the gift(s) and when gift(s) will be given:

Monetary incentive(s)

Describe the value of incentive(s), when incentive(s) will be given, and if partial payment will be offered (include information describing the conditions):

1. **Research Methods and Procedures:**
2. What data will you collect? Check all that may apply AND attach a copy of data collection instruments/tools for review (i.e. surveys, interview questions, etc.)

Surveys/Questionnaires

Individual interview

Focus group interview

Observation

Student educational records (FERPA may apply)

Protected Health Information (HIPAA may apply)

Digital data (i.e. computer, cell phone, other equipment/devices)

Other-describe:

1. Will you audio/video record or photograph participants? No Yes

If YES, check all that may apply: Audio Video Photographs

If YES, will you use audio, video, or photographs in presentations, publications, and/or training materials? No Yes *If YES, a media release form is required and your consent form modified to explicitly describe how and where you will use this material.*

1. Will you use concealment (incomplete disclosure) or deception in this study? *(NOTE: if you are requesting Exempt review under Category 2 AND your research only involves deception of the nature or purposes of the research, then check “N/A”)* N/A No Yes
2. Describe the informed consent process, include who will obtain consent from all participants, when, and how this will be done. If participants are not competent to consent for themselves, then describe procedures for obtaining consent from legally authorized representative. Attach all informed consent documents for review (including information letter, online script, and/or oral script).

**Description:**

1. Describe, in detail, your data collection methods and procedures. Describe how data will be collected, what information will be collected from participants and what sessions will be audio/video recorded and/or photographed. Provide a timeline or schedule of events, if applicable.

**Description:**

1. What is the total time (hours, minutes, days) that each participant will spend in the *entire* study, including follow-up sessions?

**Description:**

1. **Data Management Plan:**
2. Will you collect information (i.e. names, ID numbers, audio/video recording and photographs, demographic data) during the study that could identify the participants directly or through identifiers link to the participants? No Yes If NO, go to question 12. If YES, answer questions 11b-d.
3. Describe your management plan for storing and securing the data, protecting the privacy of participants and maintaining confidentiality of data.

**Description:**

1. How long will you retain identifiable data?

**Description:**

1. Will you share identifiable data with other institutions, agencies, or companies? No Yes

*Data management plan must be described on the informed consent document(s) and include details about any data that will be shared with other institutions, agencies, or companies and/or used to support future studies.*

1. **Conflict of Interest Statement/Financial Disclosure:**

Could the results of the study provide an actual or potential financial gain to you, a member of your family, or any of the co-investigators, or give the appearance of a potential conflict of interest (COI)? No Yes

If YES, contact the IRB chair to discuss disclosure requirements.

1. **PI Confirmation:**

Confirmation from the PI certifies that

* the information contained in the IRB packet is accurate and complete;
* the PI is familiar with all relevant Federal regulations and institutional policies regarding human subjects research; AND
* the PI agrees to abide by the provisions of said rules, regulations and policies and the determination of the IRB. The PI is responsible for assuring that all team members listed on the protocol are property trained and supervised and that adverse events, research-related injuries, or unexpected problems affecting the rights or safety of research participants are reported promptly to the chair of the IRB.

**Submission Instructions and IRB Review Process:** Complete IRB packets are processed as received. It is recommended that you submit your IRB application at least one month before your anticipated start date or the last day of classes in a regular (fall, spring) semester, whichever is earlier. Submit your completed IRB packet **electronically** (Word doc) to [mrollins@lander.edu](mailto:mrollins@lander.edu) .