PROTECTED SUBJECTS POPULATION/ EXEMPTION ELIGIBILITY CRITERIA

1. Are the data you propose to collect from or about any of the following protected populations: prisoners; pregnant women; fetuses; or institutionalized mentally disabled (individuals residing as patients in an institution who are mentally ill or decisionally impaired; emotionally disturbed; psychotic; or senile)?

YES ☐ NO ☐

a. If yes, then you may not apply for exemption review and must submit an IRB form for expedited or full Board review.

2. Are the data you propose to collect from or about minors? YES ☐ NO ☐

If yes, will the research involve a survey, an interview, or observations in which the investigator participates in the activities being observed? YES ☐ NO ☐

a. If yes, then exempt category 2 does not apply and you must submit an IRB form for expedited or full Board review.

3. Specify how information will be recorded? (check all that apply)

a. ☐ Information is publically available.

b. ☐ Information is recorded without identifiers or a link to a key to the codes by the investigator;

c. ☐ An independent individual, not associated with this research, will de-identify data prior to providing it to the investigator and will not provide the link to the codes.

Specify responsible individual:
Please include the names of the individuals responsible here

4. Check one or more of the appropriate exemption categories. Note: If none of the categories apply, an expedited or full Board review may be required. Please consult with IRB &KDLU for clarification.

☐ 1. Research conducted in an established or commonly accepted educational setting and involves normal educational practices such as:

• Research on regular and special education instructional strategies or
• Research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods

☐ 2. Research involving the use of:

• Educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior,

unless the information obtained is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects, 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.

NOTE: This exemption does not apply to research in the following instances:

• With children except for research involving observation of public behavior where the investigator(s) do not participate in the activities being observed or,

• If it involves human subjects who are elected or appointed public officials or candidates for public office or, Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☐ 3. Research involving the use of:

• Educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, observation of public behavior that is not exempt under paragraph category (2) above, if:

  • Research involves human subjects who are elected or appointed public officials or candidates for public office; or

  • Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

NOTE: Exemptions under this category only apply when research activities involve the following:

• Elected or appointed public officials or candidates for public office; or

• Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
☐ 4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if they are being:

- Obtained from publicly available sources or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects

**NOTE:** To qualify for Exemption 4, data, documents, records or specimens must already exist at the time the research is proposed.

☐ 5. Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

- Public benefit or service programs.
- Procedures for obtaining benefits or services under those programs.
- Possible changes in or alternatives to those programs or procedures.
- Possible changes in methods or levels of payment for benefits or services under those programs.

**NOTE:** To qualify for Exemption 5 for Public Benefit Projects, which is for projects conducted by or subject to approval of federal agencies, the following criteria must be satisfied:

- The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive or nutrition services as provided under the Older Americans Act)
- The research or demonstration project must be conducted pursuant to specific federal statutory authority.
- There must be no statutory requirement that the project be reviewed by an IRB
- The project must not involve significant physical invasions or intrusions upon the privacy of participants
- Authorization or concurrence by funding agency

☐ 6. Taste and food quality evaluation and consumer acceptance studies if:

- Wholesome foods without additives are consumed; or
- 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.
5. State the title of your research:

Click here to enter text.

**STUDY INFORMATION**

6. **Study Investigators** (All student and post doctorate applicants must list their faculty advisor as Principal Investigator below).

   Principal Investigator/Faculty Advisor: [click here to enter text]

   Department: [click here to enter text]

   Departmental Address: [click here to enter text]

   Email: [click here to enter text]

   Phone: [click here to enter text]

   Fax (if applicable): [click here to enter text]

   Student Investigator (if applicable): [click here to enter text]

   Student Year/level: [click here to enter text]

   Email: [click here to enter text]

   Phone: [click here to enter text]

   Study Contact Person: [click here to enter text]

   Email: [click here to enter text]

   Phone: [click here to enter text]

7. List all research personnel. Provide the name of their department, departmental address, e-mail address, phone number and fax number (if applicable). Use the abbreviations listed on the cover page to identify all names listed. Briefly describe their role (i.e., Research Coordinator, consent subject, administer surveys, etc.)*All student and post doctorate applicants must list their faculty advisor as Principal Investigator provide and their departmental address, phone number and e-mail address above. If more space is needed, continue on next page.

   Type your answer here

8. Is this a student project? **YES ☐ NO ☐**

   a. If yes, please check the appropriate box:

   ☐ Junior Project  ☐ Senior Thesis  ☐ Dissertation/Graduate
9. Will research be conducted outside of the United States? **YES ☐ NO ☐**

   a. If yes, complete the **International Supplement** at the end of the application and submit along with the application for review.

   b. Researchers conducting research outside the United States must comply with the relevant laws of the host country. If an international institution or site is engaged in research, and the research is supported by federal funding, additional requirements may apply.

10. If applicable, please list the agencies (University or other) that are funding or have been asked to fund this research and if funded. Attach a copy of the grant application.

   Click here to enter text.

11. State the dates for starting and ending this research project. *(Note: The project may not start until a final determination has been issued.)*

   Click here to enter text.

**RESEARCH PURPOSE**

12. Summarize the purpose of the study and the hypotheses which are to be tested.

   Click here to enter text.

13. Describe subject recruitment procedures and/or data/biological specimen collection procedures, if applicable:

   a. Provide the number of subjects to be invited to participate or the number of biological specimen/data to be collected.

   Click here to enter text.
b. Summarize the process of recruiting potential subjects. Specify inclusion and exclusion criteria when relevant and attach any recruitment announcements such as flyers, advertisements, etc. Specify how data/biological specimen will be obtained, if applicable

Click here to enter text.

c. Provide the specific name of the schools, country, clinic, or other agency from which subjects will be recruited and where the research will take place along with required permission letter(s). This should include specimen repository, databank etc. where data/specimens will be collected, when applicable.

Click here to enter text.

d. If your research plans include the collection or study of existing data, pathological or diagnostic specimens, please specify whether data will be restricted and if an agreement is in place prohibiting release of private identifiable information or the key to coded information and provide such documentation, if applicable.

Click here to enter text.
RESEARCH DESIGN

14. Describe the research design including each of the following:
   
a. Describe all research procedures as they directly affect the subject(s).
   
   Click here to enter text.

b. Include the estimated length of time for various procedures (e.g., interviews, completing
   
   Click here to enter text.

c. Questionnaires, etc.) and frequency of repetition; any manipulation including ones which may cause discomfort or inconvenience; and plans for follow-up, when applicable. This includes analysis of biological specimens/data.
   
   Click here to enter text.

d. Include a copy of questionnaires, rating scales, list of variables to be collected or other instruments to be used, if applicable.
**RISK TO SUBJECTS:**

15. Describe any potential risks including physical, psychological, social economic - monetary, reputational, legal or other potential risks.

   Click here to enter text.

**Minimal Risk** means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in the daily life or during the performance of route physical and psychological examinations or tests.

**CONSENT PROCEDURES:**

16. Describe consent procedures to be followed, including how, when, where, and by whom informed consent will be obtained, if applicable. Submit standalone consent or information sheet that is not embedded in the IRB application. Consent templates are available at the following link on the IRB d2l page:

   Click here to enter text.
17. Describe how data/study records will be kept confidential and specify safeguards to be implemented for protecting participant information and minimizing potential risks to subjects (i.e., password protected computer(s), file encryption, etc.).

Click here to enter text.

18. Training and Certification. All University personnel including students, faculty/advisor and research staff that are listed on the protocol, interact with human subjects or with identifiable subject data as part of this research project must complete human subjects training. Investigators who have not taken human subjects training must complete the University’s NIH (National Institute of Health) training program prior to initiating contact with subjects or identifiable subject. Furthermore, all third party contractors or subcontractors or collaborating institutions whose personnel will interact with human subjects or with identifiable subject data as part of this research project must either certify to the IRB that their personnel have undergone human subjects training or, they must complete the NIH training.

Please respond to the following questions:

Have all investigators identified above completed the University's training program (please check appropriate box):  YES ☐  NO ☐

If not, please have them complete the NIH human subject training and submit a copy of their training certificate. For more information about NIH training requirements,
a. Are there or will there be any third party contractors or subcontractors or collaborating institutions working on this project whose personnel will interact with human subjects or with identifiable subject data?

YES ☐  NO ☐ If yes, please append the appropriate training certification information from that entity.

Please note that the IRB will not issue a final determination unless all proper training is completed and certifications are received.

UNANTICIPATED PROBLEMS/ADVERSE EVENTS

19. Federal regulations require prompt reporting to the IRB of any unanticipated problems involving risks to subjects or others. This must be done immediately or within 10 working days. The Office for Human Research Protections (OHRP) considers unanticipated problems, in general, to include any incident, experience, or outcome that meets all of the following criteria:

- Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Your signature below certifies that you understand these criteria and agree to report any anticipated problems involving risks to subjects or others within 10 working days. Include the signature of the Investigator(s) and the date. Also include the advisor’s signature, if applicable.

Signatures

For faculty projects:
For student projects:

Faculty Advisor Assurance:
I am the faculty advisor for the student submitting this protocol. By my signature, I certify that I have reviewed the protocol and believe that it is scientifically and ethically sound. Furthermore, I believe that the student has the necessary training, experience and knowledge to conduct the research in a manner consistent with the regulations governing human subject research and sound research principles. I agree to:

- Oversee and monitor the conduct of this research by communicating regularly with the student investigator;
- Assist with the resolution of any problems or concerns encountered during the research;
- Assure that the 2UDO_5REHUWV_8QLYHUVLW\ IRB is notified in the event of an adverse event or protocol deviation.

I understand that as faculty advisor I am responsible for the conduct of this research.