PI information

This survey is for UWL faculty, staff, and students to seek an exempt status designation for a research project involving human subjects. While this survey is accessible to individuals that are currently not affiliated with UWL, exemptions are only valid if requested by and granted to a current UWL employee or currently enrolled UWL student.

Students must have mentor / advisor approval before using this tool.

Exclusions: you may **not** use this Exempt Decision Tool if any of the following are true:

- Participant incentives are being offered.
- Other institutions will be relying on UWL's IRB to provide review and oversight.
- Exemption is being claimed under exemption research categories numbered 2.c., 3.a.iii., 7, and/or 8.

Prior to completing this survey, you should review UWL's Researcher's Guide for Submission of Protocols, which is located on UWL's IRB website, to ensure that your research meets the definition of exemptible research.

You will need the following information available to complete the survey:

- Names and email addresses of any Advisors or co-PI/PDs;
- IRB training completion certificate(s) from a UWL approved course for you and any co-PI/PDs (collated into a single pdf with your certificate listed first);
- Project title and abstract, which includes the research question, independent and dependent variables, hypothesis(es), and procedures and/or activities that the subjects will undergo; and
- Basic information about the project.

If you have any questions or concerns about this survey, please contact the IRB office at irb@uwlax.edu.

What is your name and email address?

First Name
Last Name
Email address

Please select one of the following.

- ◯ Faculty/Staff
- ◯ Graduate Student
- ◯ Undergraduate Student

Will this study have either or both of the following?

- Participant incentives for research subjects
- Multiple research sites for which Reliance Agreements will be required (if you are not sure, review the Researcher's Guide and/or check with the IRB office)

- ◯ Yes
- ◯ No

What department or office is this research being conducted for?

For the question above, you selected "other". For which department or office is this research being conducted?

Are there other individuals (faculty, staff, or students) who should be listed as co-PI/PDs on this project?

A PI/PD, or principal investigator/project director, is a person responsible for the research project. Duties of a PI/PD could include preparing the protocol, conducting research, analyzing data, and reporting results.

Students: do **not** include your advisor(s) or thesis committee members here, unless they would otherwise qualify as a PI/PD (see definition above). If they are acting only in a mentoring or advisory capacity, they should be listed in later questions about advisors.

- ◯ Yes
- ◯ No

How many co-PI/PDs do you have?

List the name, status (faculty/staff, grad student, or undergrad), email address, and affiliation of your co-PI/PD(s). Complete one row per co-PI/PD; it is acceptable to have blank rows.

	First Name	Last Name	Faculty/Staff, Grad Student, or Undergraduate	Email address	Affiliation (UWL or list other)
Co-PI/PD #1					
Co-PI/PD #2					
Co-PI/PD #3					
Co-PI/PD #4					
Co-PI/PD #5					

List the name, status (faculty/staff, grad student, or undergrad), email address, and affiliation of any additional co-PI/PDs not listed in the previous question.

List the name, email address, and affiliation of your primary advisor, co-advisors, and thesis committee members. You must have a lead advisor; however, the other rows should be left blank if

you do not have co-advisors or a thesis committee.

	First Name	Last Name	Email Address	Affiliation (UWL or list other)
Lead Advisor				
Co-Advisor / Thesis Committee Member #1				
Co-Advisor / Thesis Committee Member #2				
Co-Advisor / Thesis Committee Member #3				
Co-Advisor / Thesis Committee Member #4				

Have you discussed the project with your Mentor(s)/Advisor(s) and/or, if applicable, your Thesis Committee? Reminder: in addition to discussing this project with your mentor/adisor, you must have their approval to submit to the IRB using this Exempt Decision Tool.

- ◯ Yes
- ◯ No

Please follow up with a discussion of your research in a meeting with your Advisor and then complete the decision tool. By clicking next, you will be sent to the end of the survey. You may complete it again should you and your Advisor determine that seeking an exempt designation for your project is appropriate.

Training Block

Have you (and **all** of the co-PI/PDs listed on this protocol) completed a UWL-approved IRB Online Training Course?

The approved courses are:

- CITI Human Subjects Research (Biomedical Research Investigators, Social & Behavioral Research Investigators, Research with data or laboratory specimens ONLY, or IRB Members) - UWL current training program.
- NIH Training Course - UWL's former training program - will be accepted until December 31, 2023.
- Another course that was completed prior to your affiliation with UWL **and** that has been approved for use by UWL's IRB office.

- ○ Yes
- ○ No

Please upload one (1) PDF document of the certificate(s) of completion for the mandatory IRB Online Training Course. If you have co-PI/PD(s), your certificate should be the first one in the document, and the certificate(s) for your co-PD/PD(s) should follow.

Note: the system will only accept one document, which must contain your certificate and, if applicable, the certificates for your co-PI/PD(s).

Please go to UWL's IRB website for directions on registering for and completing the required training. By clicking next, you will be sent to the end of the survey. You may complete it again should you and, if applicable, your Advisor determine that seeking an exempt designation for your project is appropriate.

Summary Block

What is the title of your project?

Please provide a brief abstract of your research project. (3,000 character maximum, including spaces)

The abstract must include the following as a description of the project:

- research question
- independent and dependent variables
- hypothesis(es)
- procedures and/or activities which the subjects will undergo

The revised **Common Rule** has set new guidelines as of 2018 of ethics in the United States regarding bio-medical and behavioral research involving human subjects.

Definition of a Human Subject:

A human subject is a living individual about whom an investigator conducting research obtains
one or more of the following:

1. data through intervention or interaction with the individual;
2. identifiable private information; and/or
3. identifiable biospecimens.

As described above, does your research include human subjects?

- ◯ Yes
- ◯ No

Secondary research

Will you be conducting secondary research (using data that already exists)?

- ◯ Yes
- ◯ No

Did research subjects sign a consent waiver that allows use of their information in secondary research?

- ◯ Yes
- ◯ No

Will you be conducting primary research (research that you will conduct to collect data)?

- ◯ Yes
- ◯ No

Please "sign" your IRB Exemption Request Form.

Your UWL person ID number will be one of the following:

- for UWL faculty / staff - your 8-digit person ID number; it is found on your pay statement and begins with 00
- for UWL students - your 9-digit student ID number

I have read the appropriate content from UWL's IRB website, and to the best of my knowledge, the information provided in this IRB Exemption Request Form is complete and correct.

First name	
Last name	
UWL Person ID number	
Today's date	

Basic research design

Will the human subjects be over the age of 18 and/or living independently?

- ◯ Yes
- ◯ No

Does your research involve any of the following?

- ☐ Educational tests
- ☐ Survey procedures
- ☐ Interview procedures
- ☐ Observation of public behavior
- ☐ None of the above

Is the identity of the subject(s) anonymous (the identity of individual subjects is not known to researchers)?

Please note that this is different from confidentiality, which is when the researcher knows the identity of a research subject, but takes steps to protect that identity from being discovered by others.

- ◯ Yes
- ◯ No

Will there be any risk of criminal or civil liability from disclosure of any responses?

- ◯ Yes
- ◯ No

Will this research be conducted in a classroom setting?

- ◯ Yes
- ◯ No

Will this project interrupt learning ability? (e.g., disrupting the ability to learn for students attending class)

- ◯ Yes
- ◯ No

Will there be interventions during this research? For example, asking them to do one of the following:

- complete a puzzle under noisy conditions;
- split a nominal amount of money between two people;
- give blood;
- perform a physical task; and/or
- solve a problem.

- ◯ Yes
- ◯ No

Will these interventions be physically invasive?

Examples of physically invasive procedures include blood draw; skin punch biopsy; bodily specimen collected by swab, debridement, or puncture; and extraction of teeth.

- ◯ Yes
- ◯ No

Are these physically invasive procedures routine? (e.g., simple blood draw)

- ◯ Yes
- ◯ Maybe
- ◯ No

Is it likely these physically invasive procedures will cause long-lasting effects?

- ◯ Yes
- ◯ Maybe
- ◯ No

Are subjects being deceived about the purpose of the research?

- ◯ Yes
- ◯ No

Will they sign a consent form informing them of the deception or will they have a prospective agreement?

- ◯ Yes
- ◯ No

Biospecimens and Food

Will the project utilize biospecimens?

- ◯ Yes
- ◯ No

Does one or more of the following apply to **all of the biospecimens** that will be used for the project?

- are human cell lines obtained from a commercial provider;
- are human cells about which all information has been published;
- are unidentifiable biospecimens/information obtained from a commercial provider; and/or
- are unidentifiable biospecimens/information obtained from a provider that is prohibited from releasing identifiers by established regulations or policies.

- ◯ Yes
- ◯ No

Were/are the biospecimens recorded anonymously?

- ◯ Yes
- ◯ No

Does the biospecimen data/information have a code linking it to identifiable, private information of living individuals?

- ◯ Yes
- ◯ No

Can the researcher readily ascertain the identities of the individuals to whom the biospecimens/information pertain? Examples of when the researcher **cannot** link the data to living individuals include:

- the key to decipher the code is destroyed before research begins;
- researchers and the holder of the key to the code enter into an agreement preventing the release of the key to researchers under any circumstances; and/or
- there are IRB-approved written policies and/or legal requirements prohibiting the release of the key under any circumstances.

- ◯ Yes
- ◯ No

Does the project involve the use of food? (e.g., taste-testing, nutritional testing, dietetics)

- ◯ Yes
- ◯ No

Will the food used in the research be FDA qualified?

- ◯ Yes
- ◯ No

Federal funding

Is the project being supported by a federal department or agency directly or via pass-through funding?

- ◯ Yes
- ◯ No

Which federal department or agency is supporting the project? Check all that apply.

- ☐ ED, including McNair
- ☐ NASA, including Wisconsin Space Grant Consortium (WSGC)
- ☐ NIH
- ☐ NSF, including WiscAMP
- ☐ Other PHS (not NIH, but including HRSA, SAMHSA, etc.)
- ☐ Other (please specify)

Signature Block

Additional materials.
You may choose to upload any additional materials about your survey that you wish to be part of the record. This could include sample interview questions, informed consent documents, etc. If you are providing these materials, they must be in a single pdf document. NOTE: Due to the nature of the Exempt Decision Tool, these materials will not be used to determine whether your protocol is exempt and may or may not be reviewed during process audits.

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