

Washington State University Human Research Protection Program (HRPP)

Office of Research Assurances

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Pullman, WA 99164-3143

Telephone: (509)335-7646 Email: irb@wsu.edu Web site: www.irb.wsu.edu

**Exemption Determination Application**

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| **HRPP Use Only – Do Not Write or Mark in This Box**  **IRB Application No:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Certified Exempt under 45 CFR 46.104(d)…**  **1  2  3  4  5  6**  **Exemption or approval not required due to:**  **Research may not be certified as exempt due to:**  **Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Print Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_** |

**NOTE: EXEMPTION CERTIFICATION IS NOT IRB APPROVAL. All STUDY MATERIALS (e.g. informed consent) SHOULD STATE THAT THE PROJECT HAS BEEN CERTIFIED AS EXEMPT OR NOT HUMAN SUBJECT RESEARCH (NHSR) BY THE WSU HUMAN RESEARCH PROTECTION PROGRAM (HRPP).**

*Instructions:*

* + - * *The WSU HRPP will determine if your project meets the federal definition(s) of human subject research or qualifies for exemption from IRB review. Do not begin data collection prior to exemption determination.*
      * *All questions must be answered, Please write "n/a" if a question does not apply.*
      * *If WSU HRPP determines that a study meets the criteria for exemption research, the regulatory requirements for informed consent do not apply. However, research that is exempt from federal regulations is not exempt from ethical standards as outlined in the* [*Belmont Report*](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/)*. This means, for example, that if potential subjects will be interviewed in a study that qualifies for exemption, they must be fully informed and free to choose whether or not to participate.*
      * *You will be informed of the HRPP’s determination via email. Please indicate in section 2 if you require “Evidence of Ethics Review” for publication, grant application or other purposes and the HRPP will generate a letter and attach it to your approval email.*

**SECTION 1. ELIGIBILITY INFORMATION**

**To determine if your study meets criteria for exemption, consider the following screening questions:**

* Categories 2 and 3 cannot involve interactions or interventions with children. (Ages under 18 are typically considered Children in the U.S.)
* If recruiting Pregnant Women: Will your procedures pose any risk to the Fetus and/or pregnancy?
* Are you specifically recruiting [prisoners](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/prisoner-research/index.html) (*subjects confined in a correctional or detention facility, including involuntary assignment to community-based alternatives to incarceration such as drug treatment facilities*)?
* Will alcohol or drugs be administered to the subjects as part of the research?
* Will blood samples be collected from participants as part of the research?
* Will biological specimens be prospectively collected from participants by noninvasive means as part of the primary research purposes?
* Will data be collected from participants using non-invasive medical procedures (*e.g., collecting blood pressure or temperature*)?
* Are live fetuses considered subjects in the research (i.e. providing specimens or imaging)?

**If you answer “YES” to any of the above questions, then your research is NOT exempt and you must fill out the non-exempt application.**

**If you answer “NO” to all the above questions, your research may be exempt. Complete the application.**

**If you have any questions, please contact the HRPP:** [**irb@wsu.edu**](mailto:irb@wsu.edu)

**SECTION 2. GENERAL INFORMATION**

1. Principal Investigator (PI) Contact Information:

(***PI must be WSU faculty or staff****, and will be the study supervisor at WSU.* ***Students, post-doctoral researchers, and visiting faculty may not serve as PI****, but may be listed as co-investigators in Section 4. All correspondence will be directed to the PI listed below*.)

Last Name:       First Name:       WSU ID #:       Position:

Department:       College/Area:       Campus:

Address/Mail Code:       Phone:       E-mail:

Please indicate which CITI training modules the PI has completed:

Biomedical or Social Behavioral Research course

Responsible Conduct of Research

Good Clinical Practice (Required for NIH funded clinical trials)

1. Study Title:
2. Is this a student’s project in which you are serving as a mentor?

Yes  No

1. Please indicate if you require a letter as evidence of ethics review for publication, grant application or other purposes.

Yes  No

1. List names of Co-investigators, Coordinators, and Key Personnel involved in this research. Include all persons who will be directly responsible for the study management, data collection, consent process, data analysis, transcription, participant recruitment, or follow up.)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| WSU I.D.# or indicate non-  WSU personnel | Name | WSU Email | CITI –WSU training completed within last 5 years? | Role in the research (Co-PI, Coordinator, Research Assistant, Transcriber, Translator, etc.) | Delegated by PI to obtain subject informed consent? |
|  |  |  | Yes  No |  | Yes  No |
|  |  |  | Yes  No |  | Yes  No |
|  |  |  | Yes  No |  | Yes  No |
|  |  |  | Yes  No |  | Yes  No |

*NOTE: If additional lines are needed, add lines or submit on a separate page.*

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| **The application will not be processed until the PI, Co-PI, and Key Personnel have completed CITI training.**   * The PI, Co-PI and Key Personnel must have completed appropriate CITI training within the last 5 years. * **Biomedical Health Sciences Researchers** must complete CITI – Good Clinical Practice **and** CITI – “Biomedical Research Course”. * **Social Behavioral Researchers** must complete CITI – “Social/Behavioral Research Course”. * For **non-WSU personnel**, provide equivalent certificates or contact the IRB to access WSU CITI training. For non-English speaking personnel, contact the IRB. * For CITI training options, visit the CITI website at <http://www.citiprogram.org> * If you have any further questions, contact the IRB Program Assistant at 335-7646 or see the webpage http://www.irb.wsu.edu/CITI.asp or email irb@wsu.edu. |

1. Estimated Study Start Date:
2. Is this research supported in whole or in part by a grant or contract?

Yes  No

**If yes**, complete below:

Funding Agency(s), Foundation, or Business:

PI on Grant/Contract:       ORSO #:

Grant Title/Contract:

1. Does the research require another institution’s approval (IRB, IBC, IACUC, Tribal IRB, local contact) or conducted in multiple locations?

Yes  No

If **yes**, complete below.

Name of the approving body(ies)/location(s):       FWA number or equivalent number:

*NOTE: The PI is responsible for securing approval and keeping a copy of the documentation. The WSU IRB’s review and Exempt Certification will cover ONLY the WSU Investigators. Any Non-WSU collaborators/staff will need to consult their respective institution’s IRB regarding their policies for collaborative research.*

1. The term “conflict of interest in research” refers to situations in which financial interests or other non-financial personal considerations (e.g. professional or personal relationships) may compromise, or have the appearance of compromising a researcher's professional judgment in conducting or reporting research.

Has any PI, Co-PI, or any other person responsible for the design, conduct, or reporting of the research received, or will receive, any personal considerations or financial assistance (other than a WSU grant or WSU award) including, but not limited to: equipment, staff, data transfers, proprietary information, or financial help? Does anyone involved in the design, conduct or reporting of research have a potential non-financial conflict of interest?

**If yes**, please describe below:

Name of the recipient(s) or individual with non-financial conflict:

Explain the assistance or potential non-financial conflict:

Explain how the potential COI will be managed below. (*If the economic interest is a “significant economic interest” as defined in* [*WSU’s Executive Policy #27*](https://policies.wsu.edu/prf/index/manuals/executive-policy-manual-contents/ep27-ethics-conflict-interest-technology-transfer/)*, you will need to obtain a management plan with the Conflict of Interest Committee.*)[[1]](#footnote-1)

1. Is the proposed research study conducted at an outside (non-WSU) facilities or entities (such as hospitals, clinics, schools, school districts, factories, offices, etc..,)?

Yes  No

**If yes**, provide the name(s) of the facility or entity:

*The researcher has an obligation to ensure that the outside entity is aware of the proposed research study and has no objections (i.e. agrees to participate). In order to respect the rights of entities, research to be conducted at these locations may require a letter from an authorized representative to the WSU IRB or researcher acknowledging the research study and their willingness to allow the proposed research.*

1. Provide the location(s) or address(es) at which research will be conducted:
2. Is the proposed research study specifically targeting Alaska Natives/Native Americans as a subject population?

Yes  No

**If yes**, in order to respect the sovereign governments, research to be conducted on Native American tribal lands will require a letter from the Tribal Council (or equivalent authorized signatory) to the WSU IRB acknowledging the research study and their willingness to allow the proposed research.

**SECTION 3. EXEMPTION CATEGORIES AND DETERMINATIONS**

*Research activities are exempt from the federal regulation 45 CFR 46.104(d) for the protection of human participants when the only**involvement of human participants falls within one or more of the categories below and are not specifically excluded from exemption as described in section 3.*

**Note: Guidance regarding categories of research eligible for exemption can be found at** [**45CFR46.104**](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML) **and on the WSU IRB web page. Please select the exempt category or categories that you believe best match your research. If you are interested in exempt categories 7 or 8, please contact the HRPP/IRB Office.**

**---------------------------------------------------EXEMPTION CATEGORY 1----------------------------------------------------------**

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 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.

**Review the following guidance before answering the questions:**

* *This research is about education and educational interventions such as educational outcomes (such as scores and grades) and classroom observations.*
* *Research certified as exempt under this category may still be subject to FERPA regulations.*

**---------------------------------------------------------EXEMPTION CATEGORY 2-------------------------------------------------------**

1. 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 (i-iii) is met.

* 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;
* Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at riskof criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; **or**
* **[If the identifiable data is sensitive in nature and]** 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 § ll.111(a)(7) . **If yes,** **you must also complete the Limited IRB Review Addendum.**

**---------------------------------------------------EXEMPTION CATEGORY 3-------------------------------------------------------**

1. 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.

* 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;
* 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
* **[If the identifiable data is sensitive in nature and]** 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 § ll.111(a)(7). **If yes, you must also complete the Limited IRB Review Addendum.**

**---------------------------------------------------EXEMPTION CATEGORY 4------------------------------------------------------**

1. 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:

* The identifiable private information or identifiable biospecimens are publicly-available;
* 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 linkedto the subjects, the investigator does not contactthe subjects, and the investigator will not re-identifysubjects;
* 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
* 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.

**----------------------------------------------------EXEMPTION CATEGORY 5------------------------------------------------------**

1. 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.

* Each federal department or agency conducting or supporting the research and demonstration project must establish, on a publicly accessible federal website 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.

**----------------------------------------------------EXEMPTION CATEGORY 6---------------------------------------------------------**

1. Taste and food quality evaluation and consumer acceptance studies, provided that one of the conditions (i or ii) below is met:

* Are wholesome foods without additives consumed?
* Does the food to be consumed contain 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 theFood and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture?

**SECTION 4. STUDY-SPECIFIC QUESTIONS (INCLUDING ETHICS & UNIVERSITY POLICIES)**

**Use lay language and avoid technical terms**

1. **Purpose**

What is the intent of the research study (hypothesis or research question)?:

1. **Participants**

Describe your participant population and how you will recruit them.

1. Describe the characteristics that you are looking for in your research subjects (*e.g. adults aged 18 and older, students in a particular math class, members of an extracurricular group)*
2. Indicate what countries data may be collected from:

United States only  European Union countries that have adoped the GDPR

Other Countries

*Note: Countries that have adopted the* [*General Data Protection Regulation*](https://ec.europa.eu/info/law/law-topic/data-protection_en) *of the European Union(GDPR) have additional data security and heavy penalties for non-compliance. Contact your departmental IT help or Central IT to make sure you are in compliance with the GDPR or any other country-specific data security regulations.*

If you are conducting survey research online, how are you restricting participation to subjects within the U.S. (e.g. limiting IP addresses, screening questions, etc.)

1. Describe anything that would cause you to exclude a particular subject (exclusion criteria) and provide justification for these exclusion factors.
2. Detail the methods and procedures that you will use to recruit participants.

*Note: When submitting, attach recruitment materials to your email, including translations if required. Recruitment materials should contain contact information for the PI, sufficient information about the study, compensation (if offered), and length of time required for subject participation.*

1. **Incentives**

Will the subjects be offered an incentive to participate or be compensated for their time? If so, describe:

*Note: You must collect social security numbesr if you are offering cash, cash cards or gift certificates in excess of $50. Payments exceeding $600 per year (including cash cards or gift certificates) require reporting to the IRS as taxable income (*[*BPPM 45.53*](http://public.wsu.edu/~forms/HTML/BPPM/45_Research/45.53_Incentive_Payments_Research_Participants.htm#Tax_Reporting)*).*

1. **Procedures**
2. Please provide a complete description of the study procedures, including the sequence, who will be completing the procedures, interventions/interactions, use of records, time required, and setting/location. These procedures should align with your respective Exempt Category(s) under Section 3:
3. For studies involving use of **secondary data**, describe the steps for acquiring, processing, and analyzing the data in order from first to last.
4. If data includes **audio or video recording**, clarify how this will be collected, stored, analyzed, and secured.
5. **Category 3 only:** If the procedures include **behavioral interventions** with adults, provide information about the intervention, or if subjects will be deceived regarding the nature or purpose of the research.

*Note: If your study includes deception , you must obtain documentation that the subjects were informed of, and agreed to, this deception, before beginning any study procedures and must adequately debrief the subjects regarding how and why they were deceived. You must submit the templates for the agreement and debriefing when submitting the application.*

1. **Data Protection and Privacy**

[Executive Policy #8](https://policies.wsu.edu/prf/documents/2017/06/ep8-university-data-policies.pdf/) describes university data policies that apply to all research projects.

1. Participant identities will not be collected at all (complete anonymity)  Yes  No
2. Participant identities will be collected separately from the data (to award credit or payments; data should be unlinked from information collected for compensation)  Yes  No
3. Participant identities are collected with the research data  Yes No
   * 1. If yes, how will you prevent the identifiable data from being released?:
     2. If yes, when will the identifying information be removed from the data, if ever?
4. Describe the location of data storage at each stage in the research process. If relevant, include WSU campus locations (with building and room numbers), off-campus sites, international sites, and cloud storage locations. For example, “Surveys will be conducted in the field on a WSU-owned tablet. Each night, data will be uploaded to the cloud and deleted from the tablet. Upon return to WSU, data will be stored on WSU-owned computer. Printed copies of data will be stored on the Pullman WSU campus in Neill Hall room 427”.)
5. Will any service be storing, processing, or transmitting data at a 3rd party facility (e.g., Microsoft Azure, AWS, Dropbox, Box or other vendor or 3rd party site)?

Yes  No

If yes, please provide the following:

1. Will the data elements will contain any information that contains identifiers and could be used to link data to an individual?
2. The name of all vendors or 3rd party services that will be used to store and process WSU data:
3. A list of data elements that will be stored, processed, or transmitted by the service(s):
4. **Data Administration**

Include the responsible parties name, title, WSU affiliation, and contact information, if not already provided in the application:

Data Custodian:       This is typically the PI of the study but may also be a departmental administrator. Data Custodian responsibilities are listed in WSU’s [Executive Policy #8](https://policies.wsu.edu/prf/documents/2017/06/ep8-university-data-policies.pdf/)

Secondary Access Person:       This person should have access to all research data and be included in the personnel list on the application. This is typically a Co-Investigator, Research assistant, ATO or other departmental designee.

Data Users, including any third party vendors (if different from the personnel list on this application):       and refer to [Executive Policy #8](https://policies.wsu.edu/prf/documents/2017/06/ep8-university-data-policies.pdf/)

1. **Retention and data management**

*The WSU Policy and Procedures Manual (BPPM 90.01) requires that all research materials be retained securely for a minimum of 3 calendar years, and destroyed/deleted thereafter.*

Please check one:

The data will be retained securely for 3 years after the completion of the research and then destroyed/deleted.

The data retention schedule is different than [BPPM 90.01](https://policies.wsu.edu/prf/index/manuals/90-00-records/90-01-research-sponsored-project-records/).

How long will data be retained?

When will identifiers be removed (master list, audio or video recordings, etc.)

What will be the final disposition of the data?

1. **Data Destruction**

Describe how data will be destroyed

*It is recommended that paper records be shredded, physical tapes be erased or physically destroyed, and electronic media be scrubbed after files are deleted. Entirely de-identified data (links to individual identity including any information that could identify participants) may be retained. See* [*BPPM 90.01*](https://policies.wsu.edu/prf/index/manuals/90-00-records/90-01-research-sponsored-project-records/)*.*

1. **Risks**

Describe any foreseeable risks (e.g. emotional or psychological discomfort, breach of confidentiality) and your plan to reduce or eliminate them:

1. **Benefits**
2. Describe any foreseeable benefit to the subjects, but do not restate the incentive/compensation above (payments or compensation may not be considered a benefit). *Research does not always directly benefit the participants.*
3. How will society benefit from your research?

**SECTION 5. INVESTIGATOR’S RESPONSIBILITIES AND ASSURANCES**

The Principal Investigator must indicate that each statement has been read, understood and will be adhered to:

1. I certify that the information provided in this application and all attachments is complete and correct
2. I understand that I have ultimate responsibility for the protection of the rights and welfare of human participants, the conduct of this study, and the ethical performance of this research
3. I agree to comply with all WSU policies and procedures, the terms of its Federal Wide Assurance, and all applicable federal, state, and local laws regarding the protection of human participants in research
4. I agree to inform participants that their participation is voluntary, what they will be asked to do, and that refusal to participate, either total or partial, will not result in penalty or punishment. Moreover, any deception will be fully disclosed and agreed to before study procedures are initiated
5. I understand that my research is subject to post-approval review by HRPP staff on behalf of the IRB
6. I attest that:
   * the study will be performed by qualified personnel according to the information in this application.
   * the equipment, facilities, and procedures to be used in this research meet recognized standards for safety.
   * all data collected for this research is the property of WSU. *Note: Refer to the “ownership” section in* [*BPPM 45.35*](https://policies.wsu.edu/prf/index/manuals/45-00-contents/45-35-managing-research-records/) *which retains rights of access and ownership both during my association with and after my separation. Refer to* [*BPPM 60.74*](https://policies.wsu.edu/prf/index/manuals/60-00-personnel/60-74-employee-departure-procedures/)*, page 4, 4th bullet under the “Facilities/Property” section.*
   * I will retain an appropriately-secured back up copy of all data in a manner compliant with WSU policies, with two WSU personnel having access to it (on a WSU central IT-approved storage system). *Note: Contact your departmental IT or Central IT for further guidance.*
   * WSU-owned data held, on non-WSU devices and/or WSU devices, will be destroyed (or retained) in accordance with [Executive Policy 8](https://policies.wsu.edu/prf/documents/2017/06/ep8-university-data-policies.pdf/). *Note: Refer to the “data retention and disposition” section in the policy, page 8.*
   * Unanticipated problems, adverse events, and new information that may affect the risk–benefit assessment for this research will be reported to the WSU HRPP Office (509-335-7646; irb@wsu.edu) and to my Departmental Chair/Director/Dean.
   * I am familiar with the latest edition of the WSU Manual for the Protection of Human Research Participants, available at www.irb.wsu.edu, and I will adhere to the policies and procedures explained therein.
   * Students and co-investigators on this study have received adequate training and are knowledgeable about the regulations and policies governing this research.
   * I agree to ensure adequate supervision of all research study personnel and to meet with the investigator(s), if different from myself, on a regular basis to monitor study progress.
7. I further certify that the proposed research has not yet been done, is not currently underway, and will not begin until exemption has been certified.

PI Name:       Signature\*: Date:

\* Only required if not submitted from the PI’s WSU email account

Before submitting this application to the HRPP, please ensure your study materials are complete:

* Completed application
* Confirm all study personnel have completed CITI training or equivalent
* Recruitment materials (script(s) for email/verbal, flier, SONA posting, MTurk posting, etc.)
* Data collection materials (surveys, questionnaires, focus group questions, interview protocols, etc.)
* Limited IRB Review Addendum if applicable

How to Submit:

* All submissions (application and the supporting materials) should be emailed to irb@wsu.edu. Subject line: “Human Subject Application, for Exempt review submission”.
* Ideally, submissions should be sent by the PI. If someone other than the PI (e.g. a graduate student, post doc, co-PI or staff) is submitting the application on behalf of PI, the submission must be copied to PI. The e-mail must come from a WSU e-mail address.

1. See also: *https://research.wsu.edu/resources-researchers/operations-support/coi/* [↑](#footnote-ref-1)