**DO NOT DELETE OR ALTER ANY PART OF THIS FORM**

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| **HRPP USE ONLY** | |
| **IRB #:** |  |
| **Rec. Log:** |  |

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| **NOT HUMAN SUBJECTS RESEARCH (NHSR) DETERMINATION** |

**Application instructions:**

* **Do not begin data collection prior to receiving a NHSR determination**.
* Do not leave questions/[REQUIRED FIELD] blank; write "**N/A**" if not applicable.
* This application is not required for departments that have developed their own procedures for NHSR determinations (e.g., program evaluation or quality improvement projects).
* For departments that do not have an alternate procedure, the WSU HRPP office will determine if your project meets the federal definition(s) of human subject research or qualifies for exemption from IRB review.
* Projects that are determined as NHSR are exempt from federal regulations. However, they are 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 project that is determined as NHSR, they must be fully informed and free to choose whether to participate.
* Any changes in the projects determined as NHSR should be re-submitted to ensure that the projects can still meet the NHSR determination.
* Institutional policies will still apply to NHSR projects (e.g., EP #8, Data Retention BPPM 90.01, etc.)
* For more information please refer to Title 45 Part 45 Section 102 (Definitions) and CFR 56.102 and 50.3 (FDA definitions).
* **The NHSR Determination is NOT IRB approval.** Do not include any language referencing IRB approval from the study materials.

**How to submit:**

* All submissions must be emailed to [irb@wsu.edu](mailto:irb@wsu.edu).
* Please have the subject line read as: **“NHSR Determination submission.”**
* Submissions **must** be sent from a WSU email account.
* When submitting, please submit all supporting material attachments as PDF or Word documents only.

**Do not submit:**

* Links (e.g., social media sites, etc.)
* Documents via cloud sharing platforms (e.g., SharePoint, Google Drive, etc.)
* Zip files
* Documents with tracked changes or comments.

**Please note:**

* Submissions are processed in the order in which they are received.

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| **SECTION 1. GENERAL INFORMATION** |

1. **Provide principal investigator (PI) contact information (a-h).** **The 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. All correspondence will be directed to the PI listed below.**
2. **PI Name:** [REQUIRED FIELD]
3. **WSU ID #:** [REQUIRED FIELD]
4. **College campus:** [REQUIRED FIELD]
5. **College area:** [REQUIRED FIELD]
6. **College department:** [REQUIRED FIELD]
7. **Address/mail code:** [REQUIRED FIELD]
8. **Phone:** [REQUIRED FIELD]
9. **Email:** [REQUIRED FIELD]
10. **Provide study information (a-c).**
11. **Study title:** [REQUIRED FIELD]
12. **Estimated start date:** [REQUIRED FIELD]
13. **Please provide a brief description of your project purpose and procedures (e.g., what type of data you will be collecting, how you will be collecting the data etc.)** [REQUIRED FIELD]
14. **Is this a student’s project in which you are serving as a mentor?**

**☐ No**

**☐ Yes**

1. **Please indicate if you require a determination on official WSU letterhead (rather than only email notification) for evidence of ethics review for publication, grant submission or other purposes.**

**☐ No**

**☐ Yes**

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| **SECTION 2. RESEARCH SCREENING QUESTIONS** |

1. **Consider the following regulatory definition and guidance for “**[**Research**](https://ori.hhs.gov/content/chapter-3-The-Protection-of-Human-Subjects-Definitions)**” before answering the screening questions (a-b).**

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| ***PLEASE NOTE:***  *The Common Rule (§ 46.102(d)) defines* [*research*](https://ori.hhs.gov/content/chapter-3-The-Protection-of-Human-Subjects-Definitions) *as:* ***“systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”***  *This means that a project meets the definition of research if it is both:*   * ***generalizable***   ***AND***   * ***systematic.*** |

1. **Is it systematic; involving a system, method, or plan that will be employed consistently throughout data collection?**

**☐ No****\****if selected, study does not meet the federal definition of research and IRB review is not needed.*

**☐ Yes**

1. **Will your conclusions be presented as representative of a larger population from which your sample was recruited?**

**☐ No***\* if selected, study does not meet the federal definition of research and IRB review is not needed.*

**☐ Yes**

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| **SECTION 3. HUMAN SUBJECT SCREENING QUESTIONS** |

1. **Consider the following regulatory definition and guidance for “**[**Human Subject**](https://ori.hhs.gov/content/chapter-3-The-Protection-of-Human-Subjects-Definitions)**” before answering the screening questions (a-d).**

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| ***PLEASE NOTE:***  *The Common Rule (§ 46.102(f)) defines* [*Human subjects*](https://ori.hhs.gov/content/chapter-3-The-Protection-of-Human-Subjects-Definitions) *as* ***“living individual(s) about whom an investigator conducting research obtains data through intervention or interaction with the individual; or identifiable private information”***  *Living Humans are considered subjects and covered by Federal regulations if the researcher:*   * ***interacts or intervenes directly*** *with them,*   *or*   * *collects* ***identifiable*** *private information.* |

1. **Does your research involve one or more living individuals?**

**☐ No\*** *if selected, study does not meet the federal definition of research and IRB review is not needed.*

**☐ Yes**

1. **Will you obtain information or biospecimens through** [**intervention or interaction**](https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46#46.102) **with the individual and use, study, or analyze the information or biospecimens?**

**☐ No**

**☐ Yes**

1. **Will you obtain and use, study, analyze or generate identifiable private information or identifiable biospecimens? Intervention or interaction with an individual are not required to meet this criterion.**

**☐ No**

**☐ Yes**

1. **Will the subject receive a test article or act as a control during a clinical trial or clinical investigation (FDA)?**

**☐ No**

**☐ Yes**

***If ”YES” to question (a) but “NO” to all other questions (b-d), your research does not involve human subjects*** *according to the federal definition(s) and* ***IRB review is not required.***

***If you answer “YES” to question (a) and “Yes” to ANY questions (b-d), your research involves human subjects*** *according to the federal definition(s).* ***You must complete either an*** [***Exempt or Non-Exempt Application***](http://www.irb.wsu.edu/forms.asp)***.***