Exempt Certification Determination Checklist

Instructions

***Prior to completing this form:***

* *Please make note of the review deadline. If unable complete and return the determination checklist by the date stated in the review assignment notice you received, contact our office* ***ASAP*** *at* [irb@wsu.edu](mailto:irb@wsu.edu)  *to request re-assignment to an alternate reviewer.*
* *Please open the submission to check for potential conflicts of interests in reviewing the submission. If a significant COI in reviewing this submission exists, contact our office* ***ASAP*** *at* [irb@wsu.edu](mailto:irb@wsu.edu) *to request re-assignment to an alternate reviewer.*

***When completing this form:***

* *Do not delete or re-format any portion of this form.*
* *Do not utilize tracked changes or comments features.*
* *Do not leave any white response field blank. If a determination or a response field is not applicable, please respond as “N/A.”*
* *Required changes/clarifications/request for additional attachments should be directed and clearly reference the relevant materials/sections/text in question for recipient understanding regarding where to address the comments and why they are being required.*
* *Ensure a single review determination has been appropriately indicated.*

*If you have questions regarding the submitted application and supporting materials or appropriate level of review/determination, please contact our office at* [*irb@wsu.edu*](mailto:irb@wsu.edu) *with a subject line of “Reviewer Guidance Request IRB # (#####-###)”* ***prior*** *to submission and an HRPP coordinator will respond at their earliest availability. Virtual guidance meetings with the WSU HRPP staff are available upon request and subject to staff availability.*

***When submitting this completed form:***

* *Upload the completed form back into to your assigned SharePoint folder.*
* *Email our office by replying to the reviewer assignment notice you received to alert our office that your review is complete and ready to be downloaded and processed.*

***IMPORTANT:*** *Incomplete forms are unable to be processed and reviewer comments are unable to be finalized or sent to the PI until a completed determination is received by our office. Submission of incomplete forms may result in significant delays in review timelines.*

**Exempt Review Considerations**

Considerations for Determining Eligibility and Project Status

If the answer to any of the questions below is “No,” required changes, clarifications, or additional attachments may be required at the discretion of the assigned reviewer. When reviewing, consider the following:

* Are all required fields complete?
* If a FCOI has been indicated, does the reviewer agree that a suitable management strategy has been developed to protect the rights and welfare of human research participants and the integrity of the institution?
* If a NFCOI has been indicated, does the reviewer agree that a suitable management strategy has been developed to protect the rights and welfare of human research participants and the integrity of the institution?
* Does the reviewer agree that the proposed purposeful inclusion of vulnerable populations is justified and that adequate safeguards are in place to protect participants?
* Does the reviewer agree that the proposed population allows for the equitable selection of subjects, and that if applicable, sufficient scientific and ethical justification for excluding classes of persons who might benefit from the research has been provided?
* Does the reviewer agree that the proposed recruitment of participants will be conducted in a fair and equitable manner?
* Does the reviewer agree that there is an established and adequate prospective consent process?
* If the proposed data retention schedule is different than [BPPM 90.01](https://policies.wsu.edu/prf/records-retention-and-disposition/research-sponsored-project-records/), does the reviewer agree that there is sufficient justification for its necessity?
* Does the reviewer agree that the proposed data storage platforms comply with current WSU policies as outlined in the [WSU Cloud Acceptable Use Matrix](https://its.wsu.edu/information-security/wsu-cloud-acceptable-use-matrix/)?
* Does the reviewer agree that the proposed data destruction procedures comply with current WSU policies as outlined in [BPPM 90.01](https://policies.wsu.edu/prf/index/manuals/business-policies-and-procedures-manual/bppm-90-01/)?
* Does the reviewer agree that the proposed incentive procedures comply with current WSU policies as outlined in [BPPM 45.53](https://policies.wsu.edu/prf/index/manuals/business-policies-and-procedures-manual/bppm-45-53/)?
* Does the reviewer agree that the proposed extra credit incentive procedures provide sufficient alternatives to be made available to the entire student pool?
* Does the reviewer agree with the stated benefits?
* Does the reviewer agree that the indicated risks are an accurate and comprehensive list?
* Does the reviewer agree that the associated risks are not greater than those experienced in regular daily life (e.g., minimal risk)?
* Does the reviewer agree that the associated risks have been sufficiently minimized or mitigated?
* Were all required applicable attachments included?
* Were all minimally required elements as outlined in the current WSU HRPP [Recruitment and Advertising Guidance](https://irb.wsu.edu/forms/), included in the submitted recruitment materials?
* Were all minimal required elements, as outlined in the current WSU HRPP [Informed Consent Guidance](https://irb.wsu.edu/forms/)and [Assent Guidance](https://irb.wsu.edu/forms/) , included in the submitted informed consent/assent/permission materials?
* Does the reviewer agree that the data collection tools are adequately designed to support the research aims and any identifiable information collected is essential to the proposed purpose of the research?
* Does the reviewer agree that there is continuity of information through the submitted materials?
* Does the reviewer agree that there is sufficient information provided to determine if the proposed research meets the federal definition of **both** “[human subjects” and “research](https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c1)” **and** is able to determine if the research meets the necessary conditions under **one or more** of the exempt categories: [Exemption 45 CFR 46.104(d)(1)](https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c3)-(6)?

Optional Reviewer Notes

Optional reviewer notes are for reviewer’s use only and will not be processed or sent to the PI.

List all notes below.

“N/A”

Reviewer Determinations

Determination of Exempt Certification Eligibility

Select **all** determinations listed below that apply.

**Eligible under** [**Exemption 45 CFR 46.104(d)(1)**](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104#p-46.104(d)(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.

**Eligible under** [**Exemption 45 CFR 46.104(d)(2)(i)**](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104#p-46.104(d)(2)(i))**:** 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 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. This condition **may be applied to research involving children as participants only if** the investigator(s) do not participate in the activities being observed per [§46.104(3)(d)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html).

**Eligible under [Exemption 45 CFR 46.104(d)(2)(ii)](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104" \l "p-46.104(d)(2)(ii)):** 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 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.This condition **may be applied to research involving children as participants only if** the investigator(s) do not participate in the activities being observed per [§46.104(3)(d)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html).

**Eligible under** [**Exemption 45 CFR 46.104(d)(2)(iii)**](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104#p-46.104(d)(2)(iii))**:** 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 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. For certification eligibility under this condition, the reviewer agrees that when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data as stipulated by the **limited IRB review requirements** outlined in [§46.111(a)(7)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111(a)(7)). This condition **may not be applied to research involving children as participants** per [§46.104(3)(d)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html).

**Eligible under** [**Exemption 45 CFR 46.104(d)(3)(i)(A)**](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104#p-46.104(d)(3)(i)(A))**:** Research involving [benign behavioral interventions](https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-august-2-2017.html) 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 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. This condition **may not be applied to research involving children as participants** per [§46.104(3)(d)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html)

**Eligible under** [**Exemption 45 CFR 46.104(d)(3)(i)(B)**](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104#p-46.104(d)(3)(i)(B))**:** Research involving [benign behavioral interventions](https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-august-2-2017.html) 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 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. This condition **may not be applied to research involving children as participants** per [§46.104(3)(d)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html)

**Eligible under** [**Exemption 45 CFR 46.104(d)(3)(i)(C)**](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104#p-46.104(d)(3)(i)(C))**:** Research involving [benign behavioral interventions](https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-august-2-2017.html) 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 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. For certification eligibility under this condition, the reviewer agrees that when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data as stipulated by the **limited IRB review requirements** outlined in [§46.111(a)(7)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111(a)(7)). This condition **may not be applied to research involving children as participants** per [§46.104(3)(d)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html)

**Eligible under** [**Exemption 45 CFR 46.104(d)(3)(ii):**](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104#p-46.104(d)(3)(ii)) For the purpose of this provision, [benign behavioral interventions](https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-august-2-2017.html) are [brief in duration](https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-august-2-2017.html), 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. This condition **may not be applied to research involving children as participants** per [§46.104(3)(d)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html)

**Eligible under** [**Exemption 45 CFR 46.104(d)(3)(iii)**](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104#p-46.104(d)(3))**:** If the research involves deceiving the subjects regarding the nature or purposes of the research, this 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. This condition **may not be applied to research involving children as participants** per [§46.104(3)(d)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html)

**Eligible under** [**Exemption 45 CFR 46.104(d)(4)(i)**](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104#p-46.104(d)(4)(i))**:** Secondary research for which consent is not required. Secondary research uses of identifiable private information or identifiable biospecimens if the identifiable private information or identifiable biospecimens are publicly available.

**Eligible under** [**Exemption 45 CFR 46.104(d)(4)(ii)**](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104#p-46.104(d)(4)(ii)): Secondary research for which consent is not required. Secondary research uses of identifiable private information or identifiable biospecimens, if 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.

**Eligible under** [**Exemption 45 CFR 46.104(d)(4)(iii)**](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104#p-46.104(d)(4)(iii)): Secondary research for which consent is not required. Secondary research uses of identifiable private information or identifiable biospecimens, if 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](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-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](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-164/subpart-E/section-164.501) or for "public health activities and purposes" as described under [45 CFR 164.512(b)](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-164/subpart-E/section-164.512#p-164.512(b)).

**Eligible under** [**Exemption 45 CFR 46.104(d)(4)(iv)**](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104#p-46.104(d)(4)(iv)): Secondary research for which consent is not required. Secondary research uses of identifiable private information or identifiable biospecimens, if the research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research 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](https://www.govinfo.gov/link/uscode/44/3501), 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](https://www.govinfo.gov/link/uscode/5/552a), and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, [44 U.S.C. 3501](https://www.govinfo.gov/link/uscode/44/3501) *et seq.*

**Eligible under** [**Exemption 45 CFR 46.104(d)(5)(i)**](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104#p-46.104(d)(5)(i))**:** 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 projects must establish, on a publicly accessible Federal Web site 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.

**Eligible under** [**Exemption 45 CFR 46.104(d)(6)(i)**](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104#p-46.104(d)(6)(i))**:** Taste and food quality evaluation and consumer acceptance studies if [wholesome foods](https://ask.usda.gov/s/article/What-is-meant-by-wholesome-in-regards-to-foods#:~:text=Wholesome%20means%20%22promoting%20the%20health,would%20be%20considered%20%22wholesome.%22) without [additives](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-170/subpart-A/section-170.3) are consumed.

**Eligible under** [**Exemption 45 CFR 46.104(d)(6)(ii)**](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.104#p-46.104(d)(6)(ii))**:** Taste and food quality evaluation and consumer acceptance studies 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.

**To be determined (TBD)\***

**N/A\*\***

Determination Of Project Status

Select **one** of the following determinations listed below.

**Exempt Certification Granted/Approved**

This determination is applicable only if the reviewer agrees to **all** the following:

* No revisions, clarifications, or additional attachments are required prior to the certification being granted. No re-review is required.
* Optional recommendations may be provided to the researchers as listed below but are **not required** as a condition of certification/approval being granted.
* The proposed research as outlined in the reviewed materials meets the federal definition of **both** “[human subjects” and “research](https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c1)” **and** has been determined to meet the necessary conditions under **one or more** of the exempt categories: [Exemption 45 CFR 46.104(d)(1)](https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c3)-(6),

**Deferred: Pending Minor Revisions\***

This determination is applicable only if the reviewer agrees to **all** the following:

* **Minor revisions to the reviewed materials are required\*** prior to the certification being granted. These are restricted to directed changes to the submitted and reviewed materials that do not impact the reviewer’s determination of certification eligibility or exempt category/subcategory. Re-Review is required and will be completed by the HRPP coordinator.
* Optional recommendations may be provided to the researchers as listed below but are **not required** as a condition of certification being granted.
* The proposed research as outlined in the reviewed materials meets the federal definition of **both** “[human subjects” and “research](https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c1)” **and** has been determined to meet the necessary conditions under **one or more** of the exempt categories: [Exemption 45 CFR 46.104(d)(1)](https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c3)-(6),

**Deferred: Pending Substantial Revisions\***

*This determination is applicable only if the reviewer agrees to* ***all*** *the following:*

* ***Substantial revisions to the reviewed materials are required, clarifications are required, or additional attachments are required\**** *prior to determination of eligibility or certification being granted.* *Re-Review is required and will be completed by the original assigned reviewer.*
* *Optional recommendations may be provided to the researchers as listed below but are* ***not required*** *as a condition of certification being granted.*
* *There is insufficient information to determine if the proposed research as outlined in the reviewed materials meets the federal definition of* ***both*** *“*[*human subjects*” and “*research*](https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c1)”***or*** *to determine if the proposed procedures as outlined in the reviewed materials meet the necessary conditions under* ***one or more*** *of the exempt categories:* [*Exemption 45 CFR 46.104(d)(1)*](https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c3)*-(6).*

**Exempt Certification Denied: Determined to be NHSR\*\***

*This determination is applicable only if the reviewer agrees to the following:*

* *The proposed research does not meet the federal definition of “*[human subjects” **or** “research](https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c1).”

**Exempt Certification Denied: Review Elevation Required\*\***

This determination is applicable only if the reviewer agrees to the following:

* The proposed procedures as outlined in the reviewed materials has been determined **not to meet any of the necessary conditions** as stipulated under one or moreof the exempt categories: [Exemption 45 CFR 46.104(d)(1)](https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c3)-(6),

Reviewer Comments

\*Required Revisions

Required revisions should be directed changes that clearly indicate where within the reviewed materials (file, header section, text) the requested changes should be addressed and the justification of their necessity. These comments will be sent to the PI.

List all that apply below.

Required field, type “N/A” if not applicable.

\*Required Clarifications

Required clarifications should be directed questions regarding the reviewed materials that are necessary for the reviewer to determine exempt certifications eligibility or project status. These comments will be sent to the PI.

List all that apply below.

Required field, type “N/A” if not applicable.

\*Required Additional Attachments

Required Additional attachment requests must clearly indicate what additional materials are needed and the justification of their necessity. These comments will be sent to the PI.

List all that apply below.

Required field, type “N/A” if not applicable.

Optional Recommendations

* Optional recommendations may be provided to the researchers as listed below but are **not required** as a condition of certification/approval being granted. These comments will be sent to the PI.

List all that apply below.

Required field, type “N/A” if not applicable.

\*\*Justification of Denial

For projects determined to be ineligible for exempt certification, provide a brief justification for the denial below.

Required field, type “N/A” if not applicable.

Reviewer Assertion

By completing and signing this form, the reviewer agrees to **all** the following:

* No COI exists that would impair the reviewer’s ability to evaluate the research without prejudice or prejudgment.
* All submitted materials have been reviewed in accordance with the relevant regulations, laws, and policies.
* The reviewer determination checklist is complete and will be submitted in accordance with the instructions stipulated in this form.

**Reviewer Name**

*Type first and last name below.*

Required field.

**Date Review Signed/Submitted**

Type date below.

Required field (MM/DD/YYYY).