Human Subjects Research Exempt Certification Application

Exempt Certification Eligibility Overview

Studies that qualify for exempt certification are not subject to the same federal requirements for research involving human subjects as non-exempt studies. However, investigators will retain the responsibility to protect the rights and welfare of their subjects, adhere to WSU policies, and conduct their research in accordance with the ethical principles of Justice, Beneficence, and Respect for Persons as described in the [Belmont Report](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html). Research involving both **identifiable and sensitive data** may require limited IRB review under expedited review procedures to ensure adequate protections for human subject participants ([45 CRF 46.109(a)](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.109)).

**To be eligible for exempt certification review, the following criteria must be met:**

1. The study meets the federal definition of **both** “[human subject” and “research](https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c1)”
2. The study meets the specific conditions under **one or more** of the following categories:

* [Exemption 45 CFR 46.104(d)(1)](https://www.ecfr.gov/current/title-45/part-46/section-46.104#p-46.104(d)(1))**:** Research conducted in established or commonly accepted educational settings, involving normal education practices.
* [Exemption 45 CFR 46.104(d)(2)**:**](https://www.ecfr.gov/current/title-45/part-46/section-46.104#p-46.104(d)(2))Research only including interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior.
* [Exemption 45 CFR 46.104(d)(3)](https://www.ecfr.gov/current/title-45/part-46/section-46.104#p-46.104(d)(3))**:** Research involving benign behavioral interventions and collection of information from adults with their agreement.
* [Exemption 45 CFR 46.104(d)(4)](https://www.ecfr.gov/current/title-45/part-46/section-46.104#p-46.104(d)(4))**:** Secondary research use of identifiable private information or identifiable biospecimens.
* [Exemption 45 CFR 46.104(d)(5)](https://www.ecfr.gov/current/title-45/part-46/section-46.104#p-46.104(d)(5))**:** Research studying, evaluating, or examining public benefit or service programs.
* [Exemption 45 CFR 46.104(d)(6)](https://www.ecfr.gov/current/title-45/part-46/section-46.104#p-46.104(d)(6))**:** Research involving taste and food quality evaluation of consumer acceptance studies.

**Please be aware that the following limitations and restrictions apply:**

* **Children**: Exemptions 2(i) and 2(ii) does **not** apply to research with children as participants, except for research involving observations of public behavior when the investigator does not participate in the activities being observed. Exemption 2(iii) does **not** apply to research with children as participants. Exemption 3 does **not** apply to research with children as participants (4[5 CFR 46.401(b)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html#46.401)).
* **Prisoners:** Research involving prisoners does not qualify for exemptions **except** for when research is aimed at involving a broader subject population that only incidentally includes prisoners ([45 CFR 46.104(b](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html))).

**Final determination of eligibility will be outlined in the official review determination.**

Instructions

**When completing this application:**

* Do not delete or re-format any portion of this application.
* Do not utilize tracked changes or comments features.
* Do not leave any white response field blank. If a response field is not applicable to your research, please respond as “N/A.”

If you have questions regarding the application, required supporting materials, or appropriate level of review to pursue, please contact our office at [irb@wsu.edu](mailto:irb@wsu.edu) with a subject line of “New Application Guidance Request” **prior** to submission to schedule a virtual guidance meeting with the WSU HRPP staff.

Section 1. Study Information

1. Study Title

Provide a study title to identify your project.

2. Research Type

Select all that apply.

Social/Behavioral research

Biomedical research

[Clinical trial](https://grants.nih.gov/policy/clinical-trials/definition.htm)

Section 2. Key Personnel

1. WSU Principal Investigator (PI)

Only **one** WSU faculty member or staff member who has a research requirement associated with their position may serve as the Principal Investigator (PI). The PI is responsible for the conduct of the proposed research. The PI may delegate research responsibilities to other approved [key personnel](https://irb.wsu.edu/research-terminology/) but must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate research responsibilities to. Prospective PIs are advised to review the investigator responsibilities outlined in the [HRPP Manual: Section 12](https://irb.wsu.edu/hrpp-policy-manual/) prior to serving in this role or delegating responsibilities.

| **Name**  **(First Last)** | **WSU ID #** | **WSU Email** | **WSU Phone #**  **(###)###-####** | **WSU College/Department Affiliation** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |

2. WSU Co-Investigators

Insert additional rows to table below if needed.

| **Name**  **(First Last)** | **WSU ID #** | **WSU Email** | **Delegated Responsibilities** |
| --- | --- | --- | --- |
|  |  |  |  |

3. WSU Research Assistants

Insert additional rows to table below if needed.

| **Name**  **(First Last)** | **WSU ID #** | **WSU Email** | **Delegated Responsibilities** |
| --- | --- | --- | --- |
|  |  |  |  |

4. WSU Research Coordinators

Insert additional rows to table below if needed.

| **Name**  **(First Last)** | **WSU ID #** | **WSU Email** | **Delegated Responsibilities** |
| --- | --- | --- | --- |
|  |  |  |  |

5. WSU Other Key Personnel

Insert additional rows to table below if needed.

| **Name**  **(First Last)** | **WSU ID #** | **WSU Email** | **Delegated Responsibilities** |
| --- | --- | --- | --- |
|  |  |  |  |

**6. Non-WSU Key Personnel**

Review of non-WSU key personnel listed will be the responsibility of their affiliate institution’s IRB and independent from WSU IRB review determinations. Subject to institutional approval and sponsor requirements, WSU **may** elect to enter into reliance agreements for multi-institutional exempt projects when there is a pre-existing relationship related to the project or when the project could not be practically accomplished without an agreement. More commonly, either WSU or the other institution **may** elect to “accept” the exempt determination of another institution in lieu of entering into an agreement with appropriate documentation ([HRPP Manual: Section 3.17)](https://irb.wsu.edu/hrpp-policy-manual/). If you have external collaborators, and your project is subject to Limited IRB Review under exempt 2.iii or 3.i.C, a reliance agreement for single IRB review may be required. If you believe your project may require a reliance agreement to be executed for the involvement of non-WSU key personnel, please contact our office at [irb@wsu.edu](mailto:irb@wsu.edu) to request a guidance meeting with the WSU HRPP staff **prior** to submission of this application.

Insert additional rows to table below if needed.

| **Name**  **(First Last)** | **Non-WSU Institutional Affiliation & FWA#** | **Email** | **Delegated Responsibilities** |
| --- | --- | --- | --- |
|  |  |  |  |

**ATTACHMENT REQUIRED:** If applicable, include a copy of any non-WSU IRB determinations made for all non-WSU key personnel listed in this application. The WSU PI will be responsible for securing and keeping a copy of any non-WSU IRB determinations. File names and document headers must clearly identify the supporting materials.

Section 3. Human Subjects Research Training Requirements

1. PI’s Acknowledgement of Training Requirements

**Applications will not be accepted from PIs who have not completed all the required trainings** related to ethical concerns and regulatory and institutional requirements for the protection of human subjects. While complete applications can be reviewed if the PI’s trainings are both complete and valid at the time of submission, **exempt certification will not be granted until all key personnel listed on the application have completed and are current with the required trainings**. As such, it is highly encouraged that all key personnel complete this training **prior** to submission. It will be the PI‘s responsibility to ensure competition of all initial and continuing required trainings for all key personnel ([HRPP Manual: Section 12.3)](https://irb.wsu.edu/hrpp-policy-manual/).

I have reviewed the [training requirements](https://irb.wsu.edu/training/) specific to exempt projects and understand the responsibilities regarding required trainings for all key personnel as stipulated above.

**ATTACHMENT REQUIRED:** If applicable, include a copy of all required CITI training documents for non-WSU Key personnel listed in this application. WSU key Personnel training will be verified through the CITI database upon submission by the HRPP office during initial processing. File names and document headers must clearly identify the supporting materials.

Section 4. Funding

1. Funding Type

Select all that apply.

N/A

Federal funding

Non-Federal funding

2. Funding Details

Insert additional rows to table below if needed.

| **Funding Agency Name** | **Grant Title** | **ORSO #** |
| --- | --- | --- |
|  |  |  |

***ATTACHMENT REQUIRED:*** *If applicable, include a copy of* *all grant/contract applications or awards.* *File names and document headers must clearly identify the supporting materials.*

Section 5. Conflicts of Interest

1. Disclosure of Financial Conflicts of Interest

a financial conflict of interest (FCOI) is a [significant financial interest](https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50#p-50.603(Significant%20financial%20interest)) held by an investigator or research employee and/or specified members of their family which could affect the design, conduct, or reporting of research and scholarship activities. If a financial COI is identified, the investigator or research employee, in collaboration with the [Conflict of Interest Review Committee (COIC)](https://research.wsu.edu/resources-researchers/operations-support/coi/), **must** develop a suitable management strategy developed to protect the rights and welfare of human research participants and the integrity of the institution.

Select one.

A FCOI does not exist.

A FCOI exists.

2. Financial Conflicts of Interest Details

Insert additional rows to table below if needed.

| **Name of key personnel with a financial COI**  **(First Last)** | **Summary of the FCOI and how it will be managed** |
| --- | --- |
|  |  |

**ATTACHMENT REQUIRED:** If applicable, include a copy of the final COI Management Plan. File names and document headers must clearly identify the supporting materials.

3. Disclosure of Non-Financial Conflicts of Interest

A non-financial conflict of interest (NFCOI) is a condition, other than financial, that can generate or be perceived as generating bias at any stage of the proposed research. Non-financial conflicts of interest should be eliminated when possible and effectively disclosed and managed when they cannot be eliminated.

Select one.

A NFCOI does not exist.

A NFCOI exists/may exist.

4. Non-Financial Conflicts of Interest Details

Insert additional rows to table below if needed.

| **Name of key personnel with a NFCOI**  **(First Last)** | **Summary of the NFCOI and how it will be eliminated or managed** |
| --- | --- |
|  |  |

Section 6. Study Overview

1. Research Questions/Objectives

List all research questions/objectives this study aims to address.

2. Research Purpose

Briefly provide a summary of the rationale and justification for conducting this research as it applies to any anticipated contributions to generalizable knowledge. Readers not familiar with the subject area must be able to readily understand the research purpose. Use lay language and avoid the use of undefined acronyms and technical terminology.

3. Research Study Procedures Sequence

Outline study procedures in planned sequence.

Section 7. Study Locations

1. Private Entities

The PI is obligated to ensure that any private entities (hospitals, clinics, schools, etc.) where access would otherwise be restricted unless granted permissions have no objections to the research, as outlined in this application, being conducted at their site **prior** to the research being conducted at these locations. The PI will be responsible for obtaining and maintaining documentation of any letters of support/site permissions.

List all private locations participant procedures will physically take place at.

**ATTACHMENT REQUIRED:** If applicable, include all letters of support/site permissions. File names and document headers must clearly identify the supporting materials.

2. Native American Tribal Lands

In respect of sovereign governments, research to be conducted on Native American tribal lands will require a letter from the Tribal Council (or equivalent authorized signatory) acknowledging the research study and their willingness to allow the proposed research. This includes tribes that have signed a [Memorandum of Understanding (MOU)](https://native.wsu.edu/tribalrelations/) with Washington State University. The PI will be responsible for obtaining and maintaining documentation of any letters of support/site permissions.

List all Native American tribal land locations participant procedures will physically take place at.

**ATTACHMENT REQUIRED:** If applicable, include all letters of support/site permissions. File names and document headers must clearly identify the supporting materials.

3. International Sites

Countries that have adopted the [General Data Protection Regulation (GDPR)](https://commission.europa.eu/law/law-topic/data-protection_en) of the European Union have specific data security requirements and issue heavy penalties for non-compliance. If the proposed research includes procedures or enrollment of participants outside of the United State, PIs are advised to review the [HRPP Manual: Section 5.4.3; Section 17.7](https://irb.wsu.edu/hrpp-policy-manual/) and consult with WSU IT or their department’s Area Technology Officer (ATO) for guidance regarding GDPR compliance and any other country-specific data security regulations.

List all international locations participant procedures will physically take place at.

4. Public Locations

List all generic public locations participant procedures will physically take place at.

5. Other Locations

List all other locations participant procedures will take place (e.g., internet, phone, etc.).

Section 8. Study Population

1. Inclusion Criteria

List all inclusion criteria for participant enrollment.

2. Purposeful Inclusion of Vulnerable Subjects

For research that requires the purposefully recruitment and enrollment of vulnerable populations, provide a justification for their inclusion, what additional safeguards will be utilized to protect vulnerable participants, and a summary of the researcher’s qualifications for conducting research with relevant populations.

3. Exclusion Criteria

List all exclusion criteria for participant enrollment.

4. Exclusion Justification

The IRB will not approve a study that does not provide adequately for the equitable selection of subjects given the research topic or has not provided an appropriate scientific and ethical justification for excluding classes of persons who might benefit from the research. The IRB will determine by viewing the application, protocol, and other research project materials that the selection of subjects is equitable with respect to sex, gender, age, socioeconomic status, and other characteristics of groups considered vulnerable or qualified for special protections under state or federal law ([HRPP Manual 3.6.5](https://irb.wsu.edu/hrpp-policy-manual/)).

Provide a justification for all exclusion criteria.

Section 9. Recruitment & Informed Consent/Assent/Permission

1. Recruitment

Recruitment of subjects must be conducted in a fair and equitable manner.

List and describe all planned methods and procedures.

**ATTACHMENT REQUIRED:** If applicable, include all recruitment tools. File names and document headers must clearly identify the supporting materials.

2. Eligibility Screening

List and describe all planned methods and procedures.

**ATTACHMENT REQUIRED:** If applicable, include all eligibility screener tools. File names and document headers must clearly identify the supporting materials.

3. Informed Consent (age 18+)

List and describe all planned methods and procedures.

**ATTACHMENT REQUIRED:** If applicable, include all informed consent tools. File names and document headers must clearly identify the supporting materials.

4. Assent (age 0-17)

List and describe all planned methods and procedures.

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**ATTACHMENT REQUIRED:** If applicable, include all assent tools. File names and document headers must clearly identify the supporting materials.

5. Parent/Guardian Permissions (age 0-17)

List and describe all planned methods and procedures.

**ATTACHMENT REQUIRED:** If applicable, include all parent/guardian permission tools. File names and document headers must clearly identify the supporting materials.

Section 10. Data Collection

1. Evaluation of Normal Educational Practices

List and describe all planned methods and procedures.

**ATTACHMENT REQUIRED:** If applicable, include all data collection tools. File names and document headers must clearly identify the supporting materials.

2. Surveys/Interviews/Focus Groups

List and describe all planned methods and procedures.

**ATTACHMENT REQUIRED:** If applicable, include all data collection tools. File names and document headers must clearly identify the supporting materials.

3. Observations of Public Behavior

List and describe all planned methods and procedures.

**ATTACHMENT REQUIRED:** If applicable, include all data collection tools. File names and document headers must clearly identify the supporting materials.

4. Behavioral Interventions

List and describe all planned methods and procedures.

**ATTACHMENT REQUIRED:** If applicable, include all data collection tools. File names and document headers must clearly identify the supporting materials.

5. Secondary Data

List and describe all planned methods and procedures.

**ATTACHMENT REQUIRED:** If applicable, include all data collection tools. File names and document headers must clearly identify the supporting materials.

6. Taste/Food Quality Evaluations

*List and describe all planned methods and procedures.*

**ATTACHMENT REQUIRED:** If applicable, include all data collection tools. File names and document headers must clearly identify the supporting materials.

7. Other

List and describe all planned methods and procedures.

**ATTACHMENT REQUIRED:** If applicable, include all data collection tools. File names and document headers must clearly identify the supporting materials.

Section 11. Data Administration

1. Data Owner

This is typically the PI of the study and must comply with the [Information Owner responsibilities](https://policies.wsu.edu/prf/index/manuals/executive-policy-manual/ep08/#Administration) under WSU Executive Policy #8.

| **First Last Name** | **Title** | **Affiliation** | **Contact Information** |
| --- | --- | --- | --- |
|  |  |  |  |

2. Data Custodian

This is typically a departmental administrator such as the Dean of a College, but also might be an Area Technology Officer (ATO) that the Dean or Area Administrator has delegated the [Data Custodian responsibilities](https://policies.wsu.edu/prf/index/manuals/executive-policy-manual/ep08/#Administration) to under WSU Executive Policy #8.

| **First Last Name** | **Title** | **Affiliation** | **Contact Information** |
| --- | --- | --- | --- |
|  |  |  |  |

3. Other Data Users

This includes any specific responsible individual affiliated with third-party vendors that must comply with the [Data User responsibilities](https://policies.wsu.edu/prf/index/manuals/executive-policy-manual/ep08/#Administration) under WSU Executive Policy #8.

Insert additional rows to table below if needed.

| **First Last Name** | **Title** | **Affiliation** | **Contact Information** |
| --- | --- | --- | --- |
|  |  |  |  |

Section 12. Data Retention Schedule

1. Anonymous/De-Identified Data Will Be Retained In Compliance With[BPPM 90.01](https://policies.wsu.edu/prf/records-retention-and-disposition/research-sponsored-project-records/)

Select one.

N/A

No

Yes

2. Identifiable Data Will Be Retained In Compliance With [BPPM 90.01](https://policies.wsu.edu/prf/records-retention-and-disposition/research-sponsored-project-records/)

Select one.

N/A

No

Yes

3. Identifiable Data Retention Schedule Is Different Than [BPPM 90.01](https://policies.wsu.edu/prf/records-retention-and-disposition/research-sponsored-project-records/)

Please be advised that if requesting a retention schedule that is different than the approved schedule outlined in BPPM 09.01, the PI must confer with the Data Custodian to ensure that the proposed retention period is consistent with WSU departmental policy.

Select one.

N/A

No

Yes

4. Alternative Data Retention Schedule if Different Than [BPPM 90.01](https://policies.wsu.edu/prf/records-retention-and-disposition/research-sponsored-project-records/)

Provide a summary of the proposed alternate data retention schedule and justification for its necessity.

**ATTACHMENT REQUIRED:** If applicable, attach the Data Custodian’s support/approval of the proposed alternative schedule. File names and document headers must clearly identify the supporting materials.

Section 13. Data Management and Protections

1. Data Storage

*PI’s are advised to review the* *[WSU Cloud Acceptable Use Matrix](https://its.wsu.edu/information-security/wsu-cloud-acceptable-use-matrix/) for guidance on the currently permitted platforms for the collection, analysis, and storage of research data. The PI will be responsible for consulting with WSU IT regarding the use of third-party platforms and obtaining any necessary contracts and permissions prior to use.*

*For each data set,* *identify and describe the planned storage locations/platforms throughout each stage of the research process.*

Insert additional rows to table below if needed.

| **Data set** | **Location/platform** |
| --- | --- |
|  |  |

**ATTACHMENT REQUIRED:** If applicable, include all approved third-party platform contracts and permissions. File names and document headers must clearly identify the supporting materials.

2. Data Confidentiality

For each data set, identify the levels of confidentiality (e.g., Intentionally identified, confidential coded, confidential unlinked, anonymous) throughout each stage of the research process.

Insert additional rows to table below if needed.

| **Data set** | **Level of confidentiality** |
| --- | --- |
|  |  |

Section 14. Data Destruction

1. Paper Records Destruction Procedures

In compliance with [Executive Policy #8](https://policies.wsu.edu/prf/index/manuals/executive-policy-manual/ep08/#:~:text=Data%20Retention%20and%20Disposition&text=Care%20must%20be%20taken%20to,outside%20of%20the%20WSU%20system.) and [BPPM 90.01](https://policies.wsu.edu/prf/index/manuals/business-policies-and-procedures-manual/bppm-90-01/), confidential records must be made illegible prior to disposal. Paper records should be destroyed by shredding. Departments may shred records with a departmentally owned shredder, hire a private shredding company, or have the records shredded by WSU Waste Management.

Describe all planned procedures.

2. Non-Paper Records Destruction Procedures

In compliance with [Executive Policy #8](https://policies.wsu.edu/prf/index/manuals/executive-policy-manual/ep08/" \l ":~:text=Data%20Retention%20and%20Disposition&text=Care%20must%20be%20taken%20to,outside%20of%20the%20WSU%20system.) and [BPPM 90.01](https://policies.wsu.edu/prf/index/manuals/business-policies-and-procedures-manual/bppm-90-01/), confidential records must be made illegible prior to disposal. Media must be physically destroyed, or digital records must be securely deleted with a suitable software program. Please contact your WSU College or Area IT support unit, Area Technology Officer, or WSU ITS for guidance prior to submission to ensure adequate destruction measures are in place.

Describe all planned procedures.

Section 15. Incentives

1. Cash/Gift Cards

*In compliance with* *[BPPM 45.53](https://policies.wsu.edu/prf/index/manuals/business-policies-and-procedures-manual/bppm-45-53/), monetary payments to participants must be limited to an amount equivalent to no more than $60 per hour when prorated ($1 per minute) to account for actual time of participation. The PI will be responsible for maintaining a log of incentive payments issued with all required elements and report to Accounts Payable when applicable. Incentive payments to a research participant totaling $600 or more annually are tax reportable.*

*Describe all planned procedures including type of gift card, amount, when and how it will be issued to participants, and any stipulations for receipt.*

2. Crowdsourcing

*In compliance with* [*BPPM 45.53*](https://policies.wsu.edu/prf/index/manuals/business-policies-and-procedures-manual/bppm-45-53/)*, Prolific and Amazon MTurk are the WSU approved crowdsourcing payment services. Use of any other crowdsourcing payment services must undergo an ITS security review and researchers* ***must****submit the approved ITS authorization.*

*Describe all planned procedures including type of platform, amount, when and how it will be issued to participants, and any stipulations for receipt.*

**ATTACHMENT REQUIRED:** If applicable, attach the approved ITS authorization. File names and document headers must clearly identify the supporting materials.

3. Tangible Personal Property

*In compliance with* [*BPPM 45.53*](https://policies.wsu.edu/prf/index/manuals/business-policies-and-procedures-manual/bppm-45-53/)*, Tax reporting using a Record of Distribution and Request for Taxpayer Number and Certification (Substitute W-9) is required for items valued at more than $200.*

*Describe all planned procedures including type of property, quantity, and monetary value, when and how it will be issued to participants, and any stipulations for receipt.*

**4. Extra Credit**

*If extra credit is offered as an incentive in exchange for participation, an alternate means of earning equivalent extra credit for an equivalent commitment of time and effort should be made available to the entire student pool.*

*Describe all planned procedures including amount , when and how it will be issued to participants, any stipulations for receipt.*

5. Other

*Describe all planned procedures including amount, when and how it will be issued to participants, any stipulations for receipt.*

Section 16. Benefits

1. Direct Benefits to Participants

While studies that involve an intervention could have an anticipated direct benefit, most research will not have foreseeable direct benefits to enrolled participants. Please note that the IRB does not consider participating in the research process or reflection on experiences a direct benefit. Likewise, the IRB does not consider incentives and payments issued to participants a benefit.

List all that apply.

2. Indirect Benefits to Society/Other Benefits

List all that apply.

Section 17. Risks

1. Foreseeable potential risks to participants

Research may be considered minimal risk if the risks of the research are not greater than those experienced in regular daily life.

Select all that apply.

None

Breach of confidentiality

Psychological harm

Social harm

Economic harm

Legal harm

Physical harm

2. Risk Reduction Plan

Describe how each above selected risk will be minimized or mitigated by the researchers.

Application Submission Instructions

Complete applications and required supporting attachments **must** be submitted as unprotected PDF file attachments by email to [irb@wsu.edu](mailto:irb@wsu.edu) with an email subject line of “New Exempt Certification Application” by the WSU PI from their WSU email account. Do **not** submit required supporting attachments as zip files, links, or via cloud sharing platforms.

If WSU key personnel listed on the application are submitting materials or corresponding on behalf of the WSU PI, the WSU PI **must** be Cc’d at their WSU email for all project related matters.

***Include all the applicable following attachments in your submission:***

* *Exempt certification Application.*
* *Non-WSU IRB determinations made for non-WSU key personnel listed in this application.*
* *Required CITI training documents for non-WSU Key personnel listed in this application.*
* *Grant/contract applications or awards.*
* *FCOI Management Plans.*
* *Letters of support/site permissions.*
* *Participant facing recruitment tools.*
* *Participant facing eligibility screener tools.*
* *Participant facing informed consent/Assent/Permission tools.*
* *Participant facing data collection tools.*
* *Data Custodian’s support/approval of the proposed alternative schedule.*
* *Third-party platforms approvals*
* *Crowdsourcing ITS authorizations*

*File names and document headers must clearly identify the supporting materials.*