Human Subjects Research 118 Designation Request

118 Designation Overview

This form is only to grant a designation under [45 CFR 46.118](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.118) for applications and proposals being considered for funding from federal agencies and departments that lack definitive plans for involvement of human subjects.

This provision may vary by funding agency. Please verify that the funding agency will accept the designation before submitting the form.

Instructions

***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 response field is not applicable to your research, please respond as “N/A.”*

*If you have questions regarding this form, please contact our office at* [*irb@wsu.edu*](mailto:irb@wsu.edu) *with a subject line of “New 118 Guidance Request”* ***prior*** *to submission.*

**Section 1. Study Information**

**1. Study Title**

*Provide a study title to identify your project.*

2. Estimated IRB Review Submission Date

Indicate the estimated date by which the investigator(s) anticipate human research plans will be definite enough to submit to IRB review.

3. Estimated Research Start Date

Indicate the estimated date by which research procedures involving human subjects is anticipated to begin.

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 ultimately 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.

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

2. WSU Co-Investigator

Insert additional rows to table below if needed.

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

3. WSU Research Assistant

Insert additional rows to table below if needed.

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

4. WSU Research Coordinator

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** |
| --- | --- | --- | --- |
|  |  |  |  |

**Section 3. Funding**

**1. Funding Type**

Select all that apply.

Federal funding

Non-Federal funding

**2. Funding Details**

Insert additional rows to table below if needed.

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

**ATTACHMENT REQUIRED:** Please include a copy of the funding proposal to the submission as a separate attachment.

Section 4. Research Overview

1. Research Questions/Objectives

Provide a summary of the research study based on the level of detail currently known. This should include, but is not limited to, what will be done, with whom, under what circumstances, for what reason..

2. Reason for 118 Designation Request

Explain why definitive plans for research with human subjects would not normally be set forth in the application or proposal, even though you have knowledge that human subjects may be involved within the period of support.

**Submission Instructions**

*A completed 118 designation request form and the 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 118 Designation Request” 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:***

* *118 Designation Request form.*
* *A copy of the funding proposal.*

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