

Human Research Protection Program (HRPP)

Standard Operating Procedure: Verifying Principle Investigator Eligibility for Human Subjects Research Protocols

Applies to: All Research Protocols submitted to the Human Research protection Program

Date: Effective Immediately (April 20, 2020)

1.0 PURPOSE: This Standard Operating Procedure (SOP) establishes guidance for Human Research Protection Program (HRPP) and Institutional Review Board (IRB) Office staff to confirm the eligibility of a WSU faculty or staff members to serve as Principle Investigator (PI) on a research project involving human subjects.

2.0 Policy Statement: To establish a standard operating procedure for identifying eligible PIs in compliance with WSU Executive Policies EP27, EP33 and EP38, regarding ethics, conflict of interest, intellectual property, tech transfer and record retention, Business Policies and Procedures Manual (BPPM) 45.35 and 90.01, and all applicable regulatory requirements (e.g. 45CFR46) for retention of data and records generated from the review and conduct of human subjects research.

2.1 Automatic eligibility to serve as PI: The following categories of faculty and staff may serve as PI on a research protocol without additional verification of eligibility:

- Tenure Accruing Faculty (full, associate, and assistant professors)
- Non-tenure-accruing research and/or clinical faculty (full, associate, and assistant professors)
- Permanent Faculty or Staff with a specific requirement to conduct research as a condition of their employment (e.g. Senior staff in Institutional Research or the Office of Civil Right/ OCR Compliance Investigation).

2.2 Eligibility to serve based on a Case-by-Case basis determination (WSU ID and e-mail address required for confirmation):

- Senior staff (non-teaching administrative and professional faculty), where a specific requirement to conduct research is not a clear condition of their employment.
- Special appointments (e.g., medical school faculty where the appointment may be equally divided between WSU and another entity), partial or affiliate appointments (e.g., medical school faculty where appointments are part time and unpaid)
- Faculty with Emeritus status
- Adjunct Faculty
- Visiting Faculty
- Visiting Scientists
- Residents (medical/pharmacy)

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2.3 **Not Eligible to serve as PI without approval by department/college and institutional official (e.g. Vice President for Research):**

- Adjoint faculty
- Postdoctoral Researcher
- Graduate Student
- Undergraduate Student
- Classified staff
- Training and student appointments
- Clinical fellows
- Unclassified hourly staff
- Lecturer or Instructor (non-faculty appointment)

3.0 **Definitions**

3.1 The definitions found in EP27 apply to this SOP.

3.2 The collective definition of Conflict of Interest (COI) includes both financial and non-financial conflicts of interest as described in all relevant WSU policies cited in this SOP.

4.0 **Responsibilities:** The Vice President for Research is responsible for Policy implementation. The Office of Research Assurances and Human Research Protection Program are responsible for implementation of this SOP to ensure compliance with University policies on behalf of the VPR.

5.0 **Procedures**

5.1 Those positions described in section 2.1, including tenure accruing track faculty and non-tenure- accruing research and/or clinical faculty, may serve as PI by default, no additional verification is required.

5.2 Those positions described in section 2.2 and 2.3 require additional department or college approval and may require approval by the institution (VPR).

5.3 Those positions described in section 2.3 also require institutional approval (VPR).

5.4 Funded projects:

5.4.1 Funded projects where the funding is received directly by WSU will have been vetted for COI through the eREX system. These externally funded projects will have been assigned an ORSO number and should be considered as having already been approved by the department/college and institution.

5.4.2 An individual listed as PI on a WSU funded project (internal funding source) that has been assigned an ORSO number has been vetted for COI through eREX and therefore already received WSU approval to serve as a PI.

5.4.3 **If the applicant PI listed on the IRB protocol differs from the PI/PD listed on the grant or contract (internal or external) PI eligibility must still be verified.**

5.4.4 For funded projects where the funding is not received by WSU (e.g. PI is direct recipient), COI has not been vetted according to institutional policy

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and the project would not be considered as having received approval from the college/department or institution and PI eligibility must still be verified.

- 5.5 PI eligibility can be verified by submission of a PI Eligibility Form, or by having the responsible administrator for the department or college submit the same information via e-mail. The minimal information set must include:
 - 5.5.1 Complete contact information from the department administrator. The administrator responsible for approvals may vary by college or department but is typically the department Chair/Director or Associate Dean for research.
 - 5.5.2 The category of appointment of the proposed Principal Investigator identifying his/her appointment and duration of the appointment
 - 5.5.3 A description of how the project aligns with the individual's responsibilities or authority over the project.
 - 5.5.4 A brief description of the qualifications of the proposed PI and the level of mentorship available, if applicable.
 - 5.5.5 A confirmation of available facilities and resources for the research.
 - 5.5.6 An attestation that the authorizing departmental or college official will ensure retention of records as required by Institutional policies or regulatory requirements.
- 5.6 For any project described in sections 5.4.3 or 5.4.4, that involves a potential COI (either financial or non-financial), the project must also be referred to either the college or university COI committee for approval (see EP27).
 - 5.6.1 IRB/HRPP staff will notify the Assistant Director (AD) of the HRPP or the Director, Office of Research Assurances of the potential COI.
 - 5.6.2 The AD or Director will refer the project for review by the appropriate conflict of interest committee.

6.0 Related Policies

6.1 EP 27, EP 33 and EP 38

6.2 BPPM 45.35 and 90.01

7.0 Key Search Words

Eligibility, PI

8.0 Revision History

1.1	Policy number	New Policy Statement

Responsible Office: Human Research Protection Program.

Policy Contact: Human Research Protection Program Assistant Director

Supersedes: Previous draft PI eligibility policies and procedures implemented by the HRPP.