**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 October 1, 2021

1. **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. **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.
   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 from academic, extension and library categories (full, associate, and assistant professors) as defined by the [Faculty Manual](https://facsen.wsu.edu/documents/2020/08/faculty-manual-2020-with-title-ix-amendments-clean-version.pdf/)
* Non-tenure-accruing research and/or clinical faculty from academic, extension and library categories (full, associate, and assistant professors) as defined by the [Faculty Manual](https://facsen.wsu.edu/documents/2020/08/faculty-manual-2020-with-title-ix-amendments-clean-version.pdf/)
* 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).
  1. **Not Eligible to serve as PI without approval by appropriate university officials from department/college *and* institutional official (e.g.** Chair/Director/AVP/etc., OR Dean/VP/Chancellor/etc., and **Vice President for Research**
* Short-term faculty(Lecturer, visiting faculty, adjunct faculty, adjoint faculty, affiliate faculty, research associate, postdoctoral research associate/fellow., postdoctoral teaching associate/fellow) and emeritus faculty (as defined by the [Faculty Manual](https://facsen.wsu.edu/documents/2020/08/faculty-manual-2020-with-title-ix-amendments-clean-version.pdf/)),
* Senior staff (non-teaching administrative and professional faculty), where a specific requirement to conduct research is not a clear condition of their employment.
* Residents (medical/pharmacy)
* Administrative professional, and other staff (as defined by [HRS](https://hrs.wsu.edu/hr-definitions-classification/))

1. **Definitions** 
   1. The definitions found in EP27 apply to this SOP.
   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.
2. **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.
3. **Procedures** 
   1. Those positions described in section 2.1, including tenure accruing track faulty and non-tenure- accruing research and/or clinical faculty, may serve as PI by default, no additional verification is required.
   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).
   3. Those positions described in section 2.3 also require institutional approval (VPR).
   4. Funded projects:
      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.
      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.
      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.**
      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 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. 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:
      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.
      2. The category of appointment of the proposed Principal Investigator identifying his/her appointment and duration of the appointment
      3. A description of how the project aligns with the individual’s responsibilities or authority over the project.
      4. A brief description of the qualifications of the proposed PI and the level of mentorship available, if applicable.
      5. A confirmation of available facilities and resources for the research.
      6. An attestation that the authorizing departmental or college official will ensure retention of records as required by Institutional policies or regulatory requirements.
   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).
      1. IRB/HRPP staff will notify the Assistant Director (AD) of the HRPP or the Director, Office of Research Assurances of the potential COI.
      2. The AD or Director will refer the project for review by the appropriate conflict of interest committee.
4. **Related Policies** 
   1. **EP 27, EP 33 and EP 38**
   2. **BPPM 45.35 and 90.01**
   3. **Faculty manual-2020**
5. **Key Search Words**

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| Eligibility, PI |

1. **Revision History**

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| 1.1 | Policy number | New Policy Statement |
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**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.