William Paterson University
Office of Sponsored Programs

Conflict of Interest and Commitment Disclosure Policy Addendum #1: Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought.

August 1, 2012

This addendum assures William Paterson University's compliance with the requirements established by the US Department of Health and Human Services' regulation on the "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service (PHS) Funding is Sought" as applicable to grants and cooperative agreements (42 CFR Part 50 Subpart F).

This addendum specifically and exclusively affects investigators or key project staff who are applying to, or involved in a project supported by, an agency within the PHS (including the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control, the Administration for Children and Families, the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, and other agencies).

- 1. This addendum assumes that (a) all employees are familiar with the *State of New Jersey Uniform Ethics Code*, (b) have completed their mandatory training, (c) always submit information on their outside activities/ employment, travel, attendance at events, scholarly capacity, and other requirements that may not be listed here, and (d) are in compliance with any management plans that may exist. Failure to comply with the *State of New Jersey Uniform Ethics Code* will negate compliance with this addendum and constitute a violation of this Policy.
- 2. A potential or actual conflict of interest (COI) exists when a significant financial interest or commitment to an outside activity would reasonably appear to affect the objectivity and independence of judgment of the employee. A significant financial interest (SFI) is anything of monetary value, including, but not limited to, remuneration in the form of salary or other payments for services (e.g., consulting fees or honoraria), equity interests (e.g., stocks, stock options, or other ownership interests), and intellectual property rights (e.g., patents, copyrights, and potential royalties from such rights). For this addendum, the following items are considered to be a SFI if they reasonably appear to be related to the covered leader's institutional responsibilities:
 - a) With regards to any publicly traded entity, a SFI exists if the value of any remuneration received from during the 12-months preceding disclosure, when aggregated, exceeds \$5,000.
 - b) With regards to any non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the covered leader or the leader's spouse or dependent children, holds any equity interest,
 - c) With regards to intellectual property rights and interests (e.g., patents and copyrights), upon receipt of income related to such rights and interests and the source of remuneration, or
 - d) With regards to travel, any reimbursed or sponsored travel related to a leader's institutional responsibilities that have not already been excluded.
- 3. The terms "investigator" and "key or covered project leader" include the project director, principal investigator or any other person, regardless of title or position, who is responsible for the design, conduct or reporting of sponsored project or research activity as well as the development and

submission of a proposal to support such work. This may include non-WPU employees who are consultants, contractors or collaborators representing agencies that will be or are partners in the sponsored project or research.

- 4. A member of the immediate family is a spouse or dependent child. The State of New Jersey Uniform Ethics Code defines the term "spouse" in very broad terms, and this definition is applied here.
- 5. Certification of training in objectivity in research and conflicts of interest by current and prospective covered project leaders who intend to assist in the development of a proposal and then engage in an externally or internally sponsored project or research is required. The certification notice must be provided to the Office of Sponsored Programs (OSP) before a proposal is submitted or before the covered project leader begins work on the project. Certification must be renewed not less than every four years from the calendar date that it was first, or subsequently, completed. WP employees may complete the approved online Conflict of Interest Course posted on the OSP's webpage.
- 6. Initial Disclosure Process for WP Employees, Un-Affiliated Consultants and Contractors, and Employees at Institutions that do not have a Conflict of Interest Policy: (a) At the time of proposal submission, when completing the Project Approval Sheet for a proposal, the applicant will identify all covered project leaders and certify that there are no SFIs. If there are SFIs or SCs, all covered project leaders involved will complete and submit a disclosure statement. (b) At time of award and annually thereafter for the duration of the award, all covered project leaders will provide an updated disclosure statement. (c) If new covered project leaders are added to the project, disclosure statements much be submitted before the appointment. (d) Disclosures will be made on standard disclosure Statement. (e) If disclosure statements are not received, proposal review and approval, the establishment of a project, and the submission of progress reports will be delayed until the statements are received.
- 7. Initial Disclosure by Non-Employees: (a) At the time of proposal submission, partnering agency will complete, sign and submit Subrecipient Commitment Form which includes questions on Conflicts of Interest. If the partnering agency does not have a PHS-compliant COI Policy, all covered project leaders will be required to adhere to WP's policy. (b) At the time for issuing a subrecipient agreement, the agreement will include a certification that the all of the covered project leaders employed by the subrecipient agency are in compliance with the subrecipient agency's COI policy. (c) If this certification is not received, proposal review and approval, the completion of subrecipient agreements, and the submission of progress reports will be delayed until the certifications are received.
- 8. Annual Disclosure: All covered project leaders will submit a new disclosure statement at least annually or as soon as a potential conflict is identified for the period of the award. Subrecipient agencies will provide certifications that all covered project leaders are in compliance with their COI policy.
- 9. *Travel Disclosure*: All key project leaders must disclose all of their travel according to their employer's policies regarding travel or attendance at events. If a key project leader's institution does not have an travel policy, or if the policy does not meet the standards of the US Department of Health and Human Services, WP's policy will be their policy.
- 10. Disclosure review and the development and supervision of management plans will occur as outlined in the Policy and Procedures on Training Certification in the Responsible Conduct of Research by Recipients and Participants in Externally Sponsored Research.