**PURPOSE:** The purpose of this Standard Operating Procedure (SOP) is to outline relationships that may produce a real or perceived institutional conflict of interest (ICOI) for research conducted at Kent State University.

**SCOPE:** This SOP applies to Principal Investigators (PIs), research personnel who conduct human subjects research under the auspices of Kent State University.

**RESPONSIBILITY:** The PI is responsible for reporting a potential or actual COI to a KSU IRB approved independent IRB for review and approval of the research. Individual research personnel who are aware of a financial or business relationship that may compromise or appear to compromise the safety or welfare of human subjects or the outcome of human subjects research are responsible for reporting the relationship to KSU Conflict of Interest Review committee for evaluation and management.

**DEFINITIONS:**

**Disclosure**: Disclosure is the formal written process of documenting all aspects relating to the development of potential intellectual property for the purpose of determining and assigning ownership.

**Gifts:** A voluntary and irrevocable transfer of money or property made in support of the University’s teaching, research and service mission without expectation of direct economic benefit or other tangible compensation commensurate with the worth of the gift. Transactions received by KSU that meet this definition will be directed to the KSU Foundation, Inc.

**Human subjects research:**  The process of conducting research AND obtaining information from human subjects in the research.

**Immediate Family:** Spouse or domestic partner, and each dependent child

**Institutional Conflict of Interest:** A situation in which the financial investments, licenses, technology transfer or patents of, or gifts to, the KSU or the personal financial interests or holdings of KSU System Senior Administrative Officials might affect, or reasonably appear to affect, institutional processes for the design, conduct, reporting, review or oversight of human subjects research. Potential ICOIs may arise in the following areas:

* when a company that has a financial or business relationship with KSU also donates a gift to KSU;
* when KSU owns equity in a company and the company has a financial or business relationship with KSU;
* when KSU licenses an invention to an entity that also has a financial or business relationship with KSU;
* when a KSU Administrative Official has a business or financial relationship with an external entity, which sponsors KSU Human Subject Research Projects.

**Investments:** Stocks, warrants, membership or other forms of equity in companies or establishments held by Kent State University, when these companies or establishments sponsor research or conduct other activities within the KSU System.

**Licensing:** Equity positions, warrants or obligations for payment held by KSU, and/or a Direct Support Organization, and/or a KSU Senior Administrative Official, when such equity, warrants or obligations for payment are derived from the licensing, sale or assignment institutional intellectual property or research materials

**KSU Senior Administrative Official:** A KSU employee or member of the KSU Board of Trustees who has direct authority over faculty appointments, salaries, promotions, and/or allocation of institutional resources, such as assignment of graduate students or other trainees, funding for space or for faculty who are conducting human subjects research.

**PROCEDURE:**

1. Individuals who are aware of a business or financial relationship that may potentially compromise the rights and welfare of human subject participants or the integrity of the research are required to report it to the IRB.
2. Each individual with a COI must report the details of the financial or business relationship via the COI form **prior to final IRB review/approval of the research.**
3. The individual with the COI will, complete the required form, and submit the COI with the research protocol attached.
4. The COI Administrator will review the conflict to determine whether if the disclosure represents an ICOI. If an ICOI exists, he/she will prepare a summary of the relevant facts and circumstances to present to the KSU COI Committee.
5. If necessary, the KSU COI Committee will develop a COI management plan to minimize or manage the conflict, or will make a recommendation regarding how the conflict may be eliminated.
6. The COI Committee will identify an individual, who will be directly responsible for ensuring that the requirements of the management plan are implemented and monitored for continued compliance.
7. Following its review, the COI Committee will communicate in writing to the IRB reviewing the research, with all of the relevant documentation that eitherthe ICOI has been eliminated in connection with the proposed human research activity ora management plan has been recommended for the IRB’s review.

1. The reviewing IRB will take action on the human subjects research, with consideration given to the management or elimination of the ICOI as recommended by the COI Committee.
2. The reviewing IRB will have final authority to decide whether the ICOI and its management, if any, allows the research to be approved.
3. If a COI management plan is determined, the designated research designee will include and attach a copy of the plan to the initial IRB submission.

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| **REFERENCES:**  | 21 CFR 54 Financial Disclosure by Clinical Investigators[PHS Regulations, "Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought" (42 CFR 50)](http://grants.nih.gov/grants/compliance/42_CFR_50_Subpart_F.htm) [NIH Guide—Objectivity in Research (July 14, 1995)](http://grants.nih.gov/grants/guide/notice-files/not95-179.html) [NSF Policy on Conflict of Interest (NSF Grants Policy Manual, Section 510)](http://www.nsf.gov/pubs/2002/nsf02151/gpm5.jsp#510) |
| **RELATED POLICIES:**  | [University Policy Regarding Financial Interest in Sponsored Projects](https://www.kent.edu/policyreg/university-policy-regarding-financial-interest-sponsored-projects) |
| **APPENDICES:**  | None |
| **REVISION HISTORY:** Keep a running history of all revision dates. |

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| **Approval Date** | **Effective Date** | **Review/Revision Date** |
|  | **01/29/2017** |  |
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