

Institutional Conflict of Interest Review for Research

Institutional Conflict of Interest (ICoI) requires review and management as described in OHSU [policy 10-01-021](#). As stated in this policy, the Integrity Program Oversight Council (IPOC) is charged with the review of ICoI. The IPOC has previously established management standards for ICoI in research. This matrix outlines, for situations where additional review is needed to determine the appropriate management, when the IPOC must review the arrangement, and when administrative review by the OHSU Research Integrity Office (ORIO) or the Conflict of Interest in Research Committee (CoIRC) may be appropriate.

<u>Type of Financial Interest/Research</u>	<u>Management Standard</u>	<u>Review Body</u>
Basic or applied science research where OHSU has a significant financial interest (SFI) as defined in 10-01-021	Public disclosure of OHSU's financial interests in publications, presentations	ORIO ¹
Minimal risk human subjects research where OHSU has an SFI	If PI does not have conflict ² : Public disclosure in publications, presentations, and in the consent form if applicable	ORIO ¹
	If PI also has conflict: -Public disclosure in publications, presentations, and in the consent form if applicable -External (outside OHSU and the financially interested business) or independent (outside business only) study monitor may be required to oversee the collection, analysis, and reporting of data.	
Greater than minimal risk human subjects research where OHSU has an SFI	If PI does not have conflict: -Public disclosure in publications, presentations, and in the consent form if applicable -External Data & Safety Monitoring Board (DSMB) may be required (*this would not typically apply in the case of gifts SFI)	CoIRC ¹
	If PI also has conflict: -Public disclosure in publications, presentations, and in the consent form if applicable -External study monitor may be required to oversee the collection, analysis, and reporting of data. -External DSMB (for some studies, an external medical monitor may be appropriate)	
Greater than minimal risk human subjects research sponsored by a company in which OHSU's SFI exceeds \$1,000,000 ³	To be determined by the IPOC based on recommendation by CoIRC	IPOC

¹ May refer to the CoIRC and/or IPOC as needed

² Including instances where the PI is the inventor of licensed technology, the PI is involved in a start-up company, or also including instances where the PI is the beneficiary of gifts from the sponsor of the research. The definition of SFI for OHSU includes gifts to the institution totaling > \$100,000 in a calendar year. In the case of gifts, whether or not the sole beneficiary of the gifts is involved in the research (including the dept chair for gifts to a dept) is a determining factor.

³ Dollar amount may consist of net sales/milestone payments or equity, and may be a value determination or realized. If equity, the IPOC should consider whether or not the trial should take place at OHSU. The rebuttable presumption standard as outlined by the [AAMC](#) should be applied. Other considerations include whether or not the investigational product/device is the sole product of the company or whether it is a larger company with a bigger portfolio