

Corrective Action Plan for Faculty Non-Adherence with Business and Research COI Management

Violation Type	Definition	Corrective Action*	Corrective Action Plan Details	Comments
Level 1	Level 1 violations include, but are not limited to, the following: <ul style="list-style-type: none"> Unintentional failure to adhere to any element of an issued business COI or research COI management plan and/or related institutional policies. Examples include: 1) Failure of a research PI to adhere to allowable \$ thresholds with the study sponsor; (2) Failure to report new outside relationships; (3) Failure to adhere to disclosure requirements. Failure to adhere to any element of an issued faculty-specific Oversight Plan 	Notification	The Office of Industry Engagement and Conflicts of Interest (“COI Office”) will notify the following individuals/groups – Conflicted Faculty Member, Principal Investigator (PI), Department Chair/Supervisor, Faculty Business Conflicts Committee (FBCC), Financial Conflicts of Interest in Research Committee (FCOIRC).	If the violation is in relationship to a FCOIR management plan and the conflicted faculty member is not the PI, the PI(s) will be informed. External agencies, such as the Office of Human Research Protection (OHRP) may also be notified, as appropriate.
		Education Session	Individualized education session conducted with the faculty member by the COI Office	Violations will be reviewed and corrective action plans will be developed by the COI Office after consultation with the FBCC and the FCOIRC, as appropriate
		Oversight	Required oversight/co-signature of future COI management plans by the Department Chair	Additional corrective actions may be needed depending on the potential magnitude of harm as assessed by the review.
Level 2	Level 2 violations include, but are not limited to, the following: <ul style="list-style-type: none"> Any repeat of Level 1 violations or Unintentional failure to adhere to any element of issued an business COI or research COI 	Notification	Faculty Member’s Department Chair/Direct Supervisor, IRB/PPHS, Research Compliance, IACUC (as relevant), the FBCC, and the FCOIRC will be apprised of repeat violation and may require additional input and corrective actions.	Violations will be reviewed and corrective action plans will be developed by the COI Office after consultation with the FBCC, FCOIRC, PPHS, Research Compliance, and IACUC, as appropriate. PPHS may recommend

	management plan(s) and/or related institutional policies resulting in harm, as assessed by the COI Office after a Level 1 review	Re-education Session with Faculty Member including the Department Chair	COI will meet with the faculty member and their Direct Supervisor, their Department Chair/Institute Director to review the management plan(s), relevant institutional policies, and if applicable, related oversight plans. The education session will reinforce steps to avoid future violations.	changes in study approvals, up to and including study suspension. External agencies, such as OHRP, may also be notified, as appropriate. The Dean of Industry Engagement and Conflicts of Interest will issue a warning letter or referral to the Dean of ISMMS for a disciplinary letter/action depending on the severity of the violation and the recommendation of the respective committees.
		Audit Requirements	If violations are related to research projects, the COI Office may require a self-audit or other audits such as Legal, Compliance, Research Compliance, and/or MSIP.	
		Acknowledgement of Error	If applicable, faculty member will sign the warning letter acknowledging the violation, confirming understanding of policy and committing to avoiding subsequent violations.	
Level 3	Level 3 violations include, but are not limited to, the following: <ul style="list-style-type: none"> Any repeat violations or Intentional failure to adhere to any element of an issued business or research management plan(s) and/or related institutional policies resulting in harm or Failure to adhere to or repeated violations of oversight requirements 	Notification	Faculty Member's Department Chair/Direct Supervisor, IRB/PPHS, Research Compliance, IACUC (as relevant), the FBCC, and the FCOIRC will be apprised of repeat violation and may require additional input and corrective actions.	Violations will be reviewed and corrective action plans will be developed by the COI Office after consultation with the FBCC, FCOIRC, PPHS, Research Compliance, and IACUC, as appropriate. PPHS may recommend changes in study approvals, up to and including study suspension. External agencies, such as OHRP, may also be notified, as appropriate. The Dean of Industry Engagement and Conflicts of Interest will make a referral to the Dean of ISMMS for review of the violation(s), with the possibility of disciplinary action(s) , in accordance to the Faculty Handbook, up to and including termination.
		Referral to the Dean	The Dean of Industry Engagement and Conflicts of Interest will make a referral to the Dean of ISMMS with recommendations from the FBCC or FCOIRC.	

* The FBCC and FCOIRC Committee Chair will retain discretion to impose a higher level of action than the standard for a particular step if warranted by the nature of the violation. For violations involving NIH sponsored studies, the FCOIRC will evaluate possible impact of violation and notify NIH if required by PHS policy.