

**FINANCIAL CONFLICTS OF INTEREST IN RESEARCH (FCOIRC)
REMEDATION PLAN FOR NON-COMPLIANCE WITH FCOIR POLICY OR PROCESS**

Approved by FCOIRC on 08/05/2013

Violation	Action¹²	Details	Notifications³
LEVEL 1	<ul style="list-style-type: none"> • Education Session 	Member of COI or Research Compliance will review policy and steps to avoid violations	<p>The FCOIRC will notify the following individuals/ groups of the violation and actions taken:</p> <ul style="list-style-type: none"> • P.I.(as applicable) • Chair/Director • IRB (if relevant) • IACUC (if relevant) <p>Any of the above can propose remediation at a higher Level.</p>
	<ul style="list-style-type: none"> • Self-Audit Requirement 	Within 30 days of education session, individual must review his/her COI responses for every project on which he/she is named on a GCO application, make corrections as required and submit a written summary of findings and actions to educator; educator will follow up with individual as required.	
	<ul style="list-style-type: none"> • Acknowledgment of Error 	Individual will sign an attestation form acknowledging the violation, confirming understanding of policy and committing to avoiding subsequent violations	
LEVEL 2	<ul style="list-style-type: none"> • Re-education of individual 	Member of COI or Research Compliance will review policy and steps to avoid violations	<p>FCOIR will notify Chair/Director and Dean in writing of violation and actions, with recommendation on how individual and department can prevent recurrences; notification will be signed by violator to indicate awareness and concurrence.</p>
	<ul style="list-style-type: none"> • Education of entire project team 	Member of COI or Research Compliance will conduct a group COI education session for the team.	
	<ul style="list-style-type: none"> • Consultation with P.I., IACUC, IRB as needed 	P.I. and IACUC/ IRB (as relevant) will be apprised of repeat violation and may offer input on corrective actions.	
	<ul style="list-style-type: none"> • Consultation w/FCOIRC 	FCOIRC will be apprised of repeat violation and planned actions, and may offer additional input.	
LEVEL 3	<ul style="list-style-type: none"> • Re-education 	With member of COI or Research Compliance	<p>FCOIR will notify Chair in writing of violation, with recommendation by FCOIRC to impose disciplinary action; Dean will be copied. Notification will be signed by violator to indicate understanding of and concurrence with plan.</p>
	<ul style="list-style-type: none"> • Consultation with P.I., FCOIRC, IACUC, IRB 	Committees will be consulted for input on further corrective actions.	

¹ The FCOIR 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.

² For violations involving NIH sponsored studies, the FCOIR will evaluate possible impact of violation and notify NIH if required by PHS policy.

³ A copy of the notification will be placed in the individual's departmental personnel file.