

**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.