

UNIVERSITY OF SOUTH ALABAMA
PHS FINANCIAL CONFLICT OF INTEREST REGULATIONS
REQUIREMENTS FOR THOSE IMPACTED BY THE NEW RULE

USA investigators receiving PHS awards:

A memorandum has been provided to ALL USA faculty, college deans, department chairs, and members of the conflict of interest committee, College Research Council, and Research Operations Council regarding the new PHS COI updates.

All active PHS Principal Investigators (PI) and applicable non-PHS PI's are identified. The Office of Research Compliance will request completion of Financial Conflict of Interest (FCOI) certification page. The PI, Co-PI and senior/key personnel (as defined on the FCOI certification page and designated by the PI as meeting the definition of "investigator" under PHS regulations) is required to complete a disclosure form to be kept on file in the departmental personnel file. Employees (i.e., faculty) who already have annual disclosure forms on file as a condition of the University Financial Conflict of Interest policy will not have to complete another disclosure. The annual disclosure that is on file at the Institution will satisfy the requirement for disclosing Financial Interests at time of grant application. An updated disclosure will need to be completed if the Investigator acquired or discovered a new Financial Interest between the time of annual disclosure and the submission of a new application.

PHS Investigators must complete FCOI training via the Collaborative Institutional Training Initiative (CITI) online program at <http://www.citi.org>. If failure to complete training occurs, PHS funding will be suspended at the time they receive their next PHS notice of award.

USA investigators receiving PHS subawards:

Investigators receiving flow down money from a PHS grant to the other institution (prime awardee) must comply with PHS FCOI regulations, and would be considered a PHS-funded Investigator under these circumstances.

If USA is the subrecipient to another entity on a PHS award, the Investigator/department may receive a request from the prime grantee asking USA to certify whether we plan to use our own FCOI policy or the prime's policy (external entity). The correct answer is to **ALWAYS** use our own policy. USA has a PHS-compliant financial conflict of interest policy and will not agree to use any other external entity's financial conflict of interest policy. If the external entity requires an authorized institutional signature, forward the form to the Authorized Official Representative for signature.

A [*Financial Conflict of Interest Disclosure*](#) form must be complete (if not already on file for all identified Investigators on the PHS award) or complete an updated disclosure if new financial interest occur as a result of the proposed research project.

Subawards issued by USA will indicate that the subrecipient organization is responsible for reviewing financial conflict of interest disclosures, and if identified, for sending notification of required information to the prime awardee institution so that it may meet reporting requirements to the PHS Awarding Component.

Collaborators, consultants, and other providers on USA PHS awards:

Other than subrecipients, it is unlikely that the PHS conflict of interest regulations apply to collaborators/consultants, etc. since they most likely will not meet PHS definition of "investigator". It is likely these individuals will NOT be responsible for the research, as they will hand over their results to one of USA's investigators and in turn the USA investigator is responsible for use of the collected

information. However, if the USA PI feels these individuals does meet the definition of “investigator” then the individual or entity follows the same process as a subrecipient.

USA subrecipients:

The University must obtain verification from each proposed subrecipient before proposal is submitted whether the proposed subrecipient has their own PHS-compliant financial conflict of interest policy or, if they don't have their own policy that they will agree to comply by the Prime's policy and process. Subrecipient's can demonstrate compliance in two ways: (i) subrecipient organization is listed on the Federal Demonstration Partnership (FDP) Clearinghouse list as a PHS FCOI compliant institution, or (ii) they do not have a policy, the subrecipient must agree to use USA's policy. In the latter case, the PI or Grants Administrator is responsible for providing the potential subrecipient with the subrecipient letter and forms packet during proposal development. The packet is available on the subrecipient resource repository website at:

<http://www.southalabama.edu/researchcompliance/phsrepository.html> Additionally, the Standard Operating Procedures on Processes for Subrecipients is located on this website.

If the subrecipient is using USA's policy, disclosures must be received before proposal submission to a PHS agency and annually thereafter, or whenever change occurs. Any potential financial conflict of interest identified via the disclosure process will be reviewed by the VP for Research at the Just-in-Time stage or at whatever later time the subrecipient notifies USA of a potential conflict.

If the subrecipient is using USA's policy, all disclosed potential financial conflict of interest must be reviewed prior to subrecipient expending any funds. Also, subrecipient key personnel meeting the definition of “investigator” must complete conflict of interest training.

PHS Updates: Financial Conflict of Interest website:

<http://www.southalabama.edu/researchcompliance/phscoirules.html>