

Summary of Changes
“Procedures for Disclosing and Addressing Conflicts of Interest”

History

Currently, there are two separate administrative procedures for managing conflicts of interest (COI), A5.504 and A8.956, with one being specific to United States Public Health Service (PHS) regulations. Since PHS is not the only funding agency with COI policies, to minimize confusion and treat COI matters uniformly, A8.956 and the portions of A5.504 relating to COI for extramural awards are being consolidated into one new administrative procedure, AP12.304. The chapter change from 8 to 12 is due to the reassignment of research related administrative procedures.

The organizational/institutional COI from A5.504 are not included in the proposed AP12.304, and it is expected that these will be subsequently addressed in a separate AP, including COI obligations under state law (Hawaii Revised Statutes Chapter 84, Standards of Conduct), i.e., conflicts of commitment. A separate AP will be forthcoming at a later date.

Changes

Applicable Section of 12.304	Description of Change
Purpose	<ul style="list-style-type: none"> • Narrows the scope of A5.504 to remove the non-Extramurally-Funded Activities, those activities covered separately under the scope of HRS Ch. 84. • Expands the scope of A8.956 to make the PHS standards applicable to all extramural funded awards.
Definitions	<ul style="list-style-type: none"> • COI – Takes definition from A5.504, but makes it applicable to “Investigators”, thus eliminating scope of HRS Ch. 84. • COIC – Takes definition from A8.956, but simplifies duties to “review and consult” on matters. • Management Plan – Creates a new definition not present in A5.504 or A8.956, but merely referred to as “Manage” in definitions of A5.504 and in procedures section of A8.956 (IV.C.2 and V.A.4). • Deciding Official – Brings title VPRI up-to-current. Formerly VPR in A5.504 and A8.956. • Disclosure – Takes the definition from A5.504 but clarifies that the discloser is making his/her disclosure to UH and not to Senior Administrators, to be in line with new electronic process. • Extramurally-Funded Activity – Creates a new definition to cover the scope of “Research” definition in A5.504 and broadens it to cover all extramural funds.

Definitions (continued)	<ul style="list-style-type: none"> • FCOI – Takes its definition from A8.956 but eliminates reference to PHS, and refers back to COI definition for uniformity. • Immediate Family – Takes definition from A5.504. There was no definition in A8.956 but spouses and dependent children were referred to in “Investigator” and “Significant Financial Interest” definitions. • Investigator – Harmonizes definitions in A5.504 and A8.956, clarifying scope (now applicable to all extramural funds) from A5.504 and removing reference to PHS from A8.956. Eliminates confusion of a separate “Senior/key personnel” definition that was in A8.956 and A5.504. • Institutional Responsibilities – Takes definition from A.504 but eliminates reference to IRB and Data and Safety Monitoring Boards. IRB is treated separately in new AP. • ORS – Takes definition from A5.504 but eliminates the complexity of the responsibilities in the definition because they are covered under Section III of new AP. • PHS – Takes its definition from A8.956 (see “HHS”) but clarifies scope of applicable regulations under two parts of the CFR. PHS is included as a separate definition because of the unique training requirement treated under III.B.6. of the new AP and the unique reporting requirement for sponsored travel in II.M.4. • SFI – Takes its definition from both A8.956 and A5.504 which were substantially similar, but carved out travel remuneration as being specific to PHS-funded Investigators. • Supervisor – Now requires that an <i>immediate</i> supervisor review disclosures, whereas this was merely referred to on Attachment A to A5.504, because this individual has the most first-hand knowledge of the Investigator’s activities. Includes a reviewer akin to the former “Senior Administrator” definition found in both A5.504 and A8.956 who have always had disclosure review responsibilities. There are now two levels of review.
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<p>Administrative Procedure, A. Responsibilities</p>	<ul style="list-style-type: none"> • Additional Investigator Responsibilities: 1) compliance with regulations; and 2) making disclosures to ORS (in line with new electronic process). • Clarification of Investigator Responsibilities: <ul style="list-style-type: none"> - In addition to complying with management plans, they have to establish one, if one is required; - Human Subjects research is now referred to here; and - Thirty (30) day disclosure timeline is now referred to here. • Removal of Investigator Responsibilities: no longer responsible for incorporating flow-down subaward terms (was in A8.956). Moved to ORS' responsibilities. • Additional ORS responsibilities: 1) certifying to UH policy in in proposals/awards; 2) sending disclosure to Investigator's Supervisors (in line with new electronic process); 3) referring cases of violations to the Deciding Official (DO); 4) consulting with UH OTTED regarding IP ownership issues; 5) providing training; 6) notifying UH Human Studies Program of identified FCOI; 7) recordkeeping (in line with new electronic process); 8) notifying federal agencies of FCOI, if required by agencies to do so; and 9) monitoring Management Plans. • Clarification of ORS responsibilities: 1) explicitly states that ORS will review disclosures, whereas this was described in A8.956 as assisting in determining FCOI; and 2) referral of cases to the COIC through the DO instead of "coordinating" them (in line with new electronic process). • Removal of ORS responsibilities: 1) no longer says that ORS is required to maintain/disseminate the policy and related regulations (was in A8.956), as the existence of the policy already accomplishes this. • Clarification of Supervisor responsibilities: 1) makes explicit the Disclosure review and Management Plan responsibilities defined in the Procedures section of A8.956. • Clarification of the DO responsibilities: 1) makes explicit the responsibilities for recommendations of Management Plans, FCOI determination, and initiating a retrospective review; and 2) clarifies how the interaction between DO and COIC would work (which was covered in A5.504). • Additional DO responsibilities: 1) imposing corrective actions and sanctions for violations (as opposed to Research Integrity Officer referred to in A5.504; and 2) appointing COIC members.
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<p>Administrative Procedure, A. Responsibilities (continued)</p>	<ul style="list-style-type: none"> • Clarification of the COIC responsibilities: 1) makes explicit the Disclosure review and Management Plan responsibilities defined in the Procedures section of A8.956. • Removal of COIC responsibilities: removes responsibility to monitor Management Plans (from A8.956). Moved to ORS' responsibilities.
<p>Administrative Procedure, B. Procedures</p>	<ul style="list-style-type: none"> • Re-orders the conditions under which a Disclosure must be reviewed/updated which were scattered throughout A.956. • Makes FCOI information available to the public upon request instead of on a UH website (was in A8.956 and A5.504). • Clarifies that instead of a mitigation report (from A8.956), ORS will simply "report", including how the FCOI was managed. • Is now explicit about what data shall be reported, as required by federal regulation. • Incorporates the Management Plan recommendations from the DO-approved template. • Now includes the regulatory requirements of a Retrospective Review, should one be required (if a COI comes to light).