

**BY ORDER OF THE COMMANDER
59TH MEDICAL WING**

**59TH MEDICAL WING INSTRUCTION
51-501**



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Law

**MANAGING CONFLICT OF INTEREST
IN RESEARCH**

COMPLIANCE WITH THIS PUBLICATION IS MANDATORY

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This instruction implements AFPD 51-5, *Administrative Law, Gifts, and Command Relationships*. This instruction outlines the managing of conflict of interest in research programs. This instruction is applicable to all personnel who are physically or administratively assigned to the 59th Medical Wing (MDW). This instruction does not apply to the Air National Guard or Air Force Reserve. This publication requires the collection and or maintenance of information protected by the Privacy Act of 1974 authorized by 10 U.S.C. 55, *Medical and Dental Care*, and E.O. 9397 (SSN). The applicable SORN F044 AF SG D, and Automated Medical/Dental Record System is available at: <http://dpclo.defense.gov/Privacy/SORNs.aspx>. Refer recommended changes and questions about this publication to the Office of Primary Responsibility using the AF Form 847, *Recommendation for Change of Publication*. The authority to waive requirements is the publication approval authority. Ensure that all records created as a result of processes prescribed in this publication are maintained IAW AFI 33-322, *Records Management and Information Governance Program*, and disposed of IAW Air Force Records Information Management System (AFRIMS) Records Disposition Schedule (RDS).

SUMMARY OF CHANGES

This publication has been revised. This rewrite of 59 MDWI 51-501 includes: Updates to reporting requirements for reviewers and updates 59 MDW Form 15, *Financial Conflict of Interest Disclosure for 59 MDW Key Personnel and Reviewers*.

1. Purpose.

1.1. The 59th Medical Wing (MDW) seeks excellence in the quality of its human subjects research, in the teaching and education it provides to its residents and trainees, and in the service it provides to the broader military and Air Force communities. As a recipient of public funds, the 59 MDW has a responsibility to ensure that human subjects research and business development activities are in the best interest of the Air Force community and that any real or apparent risks from external interests that might compromise 59 MDW decisions through influencing the judgment of the 59 MDW, or one of its members, are minimized and controlled. To guard against these external influences, the 59 MDW has put procedures in place to identify and address conflicts of interest (COI). These procedures are not intended to discourage research, creative activity, or scholarship.

1.2. This instruction provides appropriate safeguards to sustain a climate in which sponsored projects, dedicated gifts, research, scholarship, technology transfer, and business development are conducted responsibly, and in doing so, foster an atmosphere of openness and integrity. Moreover, the 59 MDW has a responsibility to ensure that no one should unfairly benefit from the public trust or reputation of the 59 MDW. Finally, research integrity and the welfare of human research participants will not be compromised, or appear to be compromised, by competing 59 MDW interests and obligations.

2. Applicability, Individuals Covered by this Instruction.

2.1. An individual conducting research is defined as an individual who, regardless of title or position, is responsible for the design, conduct, or reporting of research involving human subjects, including for example researchers or other research staff and their immediate family members.

2.2. An immediate family member includes: a spouse; dependent child or stepchild; any other person financially dependent on the individual conducting research; and any other person with whom the individual conducting research has joint financial interests such that an objective third party could reasonably conclude that the decisions of the individual conducting research or other exercise of professional responsibilities at the 59 MDW could be influenced by the effect of that action on the person's financial interest. **Note:** An immediate family member is without regard to whether a legal or biological family relationship exists with the individual conducting research. If the individual conducting research is in doubt, the individual conducting research should resolve the doubt in favor of disclosure.

2.3. 59 MDW Key Personnel and all individuals conducting or reviewing research are responsible for knowing, understanding, and complying with this policy as it relates to their role in research, or other affiliation with the 59 MDW. **Note:** Key Personnel are individuals who approve or oversee research. This term includes, but is not limited to individuals serving as: Office of the Chief Scientist (59 MDW/ST) Senior Directors and Deputies; 59 MDW/ST Program Directors for Trauma and Clinical Care Research, Clinical Investigations and Research Support, Diagnostic and Therapeutics, Nursing Research, Research Quality Assurance and Education, Protocol Office; 59 MDW/ST Project Managers; Research Managers or Monitors and Chairs of the 59 MDW Human Research Protection Program (HRPP) Steering Committee, 59 MDW Institutional Review Board (IRB), 59 MDW Scientific Ethics Subcommittee (SES), and other human subjects research-related committees that might be created in the future.

2.4. 59 MDW individuals conducting or reviewing research as well as Key Personnel must comply with the education requirements of this policy.

2.5. 59 MDW individuals conducting or reviewing research and immediate family members must comply with the disclosure requirements of this policy.

3. Researcher Financial Conflict of Interest (FCOI) Involving Human Subjects.

3.1. Financial interests should not compromise an individual's [Military, Department of Defense (DoD) Civilian, contractor, volunteer, etc.] ability to perform all the activities expected of him or her as a member of the 59 MDW.

3.2. Individuals conducting or reviewing research should not receive remuneration for conducting research at the 59 MDW except through DoD channels (e.g., salary).

3.3. Individuals conducting or reviewing research should not conduct research at the 59 MDW under circumstances in which a reasonable person would infer that the activity could have been distorted by the desire for, or expectation of, direct or indirect external economic or personal advantage.

3.4. Individuals conducting or reviewing research should not participate directly in the negotiation of research agreements [e.g., Cooperative Research and Development Agreement (CRADA)], technology license agreements, equipment purchases, or other arrangements between the 59 MDW and an organization in which the individual or family member has a significant financial interest.

4. Non-Financial Conflicts of Interest.

4.1. Outside Relationships should not compromise an individual's [Military, Department of Defense (DoD) Civilian, contractor, volunteer, etc.] ability to perform all the activities expected of him or her as a member of the 59 MDW. This includes all positions outside the U.S. Government held at any time during the reporting period whether or not the position was compensated and whether or not the person reporting currently holds that position. Positions include being an officer, director, employee, trustee, general partner, proprietor, representative or consultant of any of the following: (1) corporation, partnership, trust or other business entity, (2) non-profit or volunteer organization, (3) educational institution. Intellectual property rights and interests should also be disclosed in Part II of the disclosure form.

4.2. Non-Financial Gifts should not compromise an individual's [Military, Department of Defense (DoD) Civilian, contractor, volunteer, etc.] ability to perform all the activities expected of him or her as a member of the 59 MDW. Items such as gifts or gifts of travel should be disclosed in Part III of the disclosure form.

4.3. Commitments that interfere with the ability to commit enough time to the project should not compromise an individual's [Military, Department of Defense (DoD) Civilian, contractor, volunteer, etc.] ability to perform all the activities expected of him or her as a member of the 59 MDW.

4.4. Other disclosures that the individual has that could compromise their ability to perform all the activities expected of him or her as a member of the 59 MDW should be disclosed in Part IV of the disclosure form.

5. Key Personnel and Reviewer FCOI Involving Human Subjects.

5.1. Financial interests should not compromise an individual's [Military, Department of Defense (DoD) Civilian, contractor, volunteer, etc.] ability to perform all the activities expected of him or her as a member of the 59 MDW.

5.2. Key personnel and reviewers approving, reviewing or overseeing research should not do so under circumstances in which a reasonable person would infer that the approval or decisions made during oversight could have been distorted by the desire for, or expectation of, direct or indirect external economic or personal advantage.

5.3. Key personnel and reviewers approving, reviewing or overseeing research should not participate directly in the negotiation of research agreements (e.g., CRADA), technology license agreements, equipment purchases, or other arrangements between the 59 MDW and an organization in which the individual has a significant financial interest.

6. Education.

6.1. Individuals conducting or reviewing research must complete COI training in regards to this policy when the researcher is new to the organization before submitting first application to the Institutional Review Board (IRB), and at least every four (4) years thereafter. Individuals conducting research must complete the training immediately if the 59 MDW finds that the individual is not in compliance with this policy or the individual's management plan, or if the 59 MDW revises this policy in a manner that affects the individual's research duties.

6.2. Key personnel approving or overseeing research, and identified as such by the Office of the Chief Scientist (59 MDW/ST), must complete COI training in regards to this policy when new to the organization and before assuming approval or oversight duties, and annually thereafter. Key personnel must complete the training immediately if the 59 MDW finds that the individual is not in compliance with this policy or the individual's management plan, or if the 59 MDW revises this policy in a manner that affects the individual's duties.

6.3. The Office of the Chief Scientist (59 MDW/ST) is responsible for ensuring that appropriate staff, and other persons complete COI training in regards to this policy and applicable laws. This training will also be tracked by the COI Manager.

7. Disclosure of Significant Financial Interests Related to Individuals' Research Responsibilities.

7.1. Extent of Disclosure. As often as required by the "When to Disclose" section below, individuals conducting or reviewing research and Key Persons will complete or update a financial interest disclosure statement that discloses, as provided by the "Contents of Disclosure" section below, each significant financial interest of the individual and immediate family members that appear to be related to the individual's research responsibilities.

7.2. Contents of Disclosure: Significant Financial Interests. The following interests are considered to be significant financial interests and must be disclosed. Subject to the exclusions provided by Section 7.3, the disclosure statement for individuals conducting research must include the following information for the covered individual and their immediate family members, but only in regard to interests that reasonably appear to be related to the individual's research responsibilities:

7.2.1. Payments Received from or Equity Interest in a Publicly Traded Entity. The total amount and source of payments received in the preceding twelve months from a publicly traded entity and the value of any equity interest held in the entity on the date of disclosure that, when aggregated, exceed \$5,000, including:

7.2.1.1. As to payments received: salary; and any payment for services other than salary, such as consulting fees, honoraria, or paid authorship; and

7.2.1.2. As to equity interests held: any stock, stock options, or other ownership interest or entitlement to such an interest, valued by reference to public prices or other reasonable measures of fair market value.

7.2.2. Payments Received from or Equity Interest in a Non-Publicly Traded Entity. The total amount and source of payments received in the preceding twelve months from an entity that is not publicly traded that, when aggregated, exceed \$5,000, including:

7.2.2.1. Salary; and

7.2.2.2. Any payment for services other than salary, such as consulting fees, honoraria, or paid authorship; and

7.2.2.3. A description of any equity interest held in an entity that is not publicly traded, including any stock, stock options, or other ownership interests or entitlement to such an interest.

7.2.3. Intellectual Property and Royalties:

7.2.3.1. A description of intellectual property rights held and any agreements to share in royalties related to those rights; and

7.2.3.2. The amount and source of royalty income that the individual conducting research or immediate family member received or had the right to receive in the preceding twelve months.

7.2.4. Gifts and Travel. Individuals conducting research must disclose gifts, including gifts of travel, having a market value exceeding \$20 per source per occasion and gifts from a single source with an aggregate market value exceeding \$50 in a calendar year.

7.3. Contents of Disclosure. Non-Significant Financial Interests. The following interests are not significant financial interests and need not be disclosed on the disclosure statement:

7.3.1. Salary, royalties, or other remuneration paid by the 59 MDW to the individual conducting research, if the individual conducting research is currently employed or otherwise appointed by the 59 MDW;

7.3.2. Income from seminars, lectures, or teaching engagements sponsored by a federal, state, or local government, an institution of higher education as defined by 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a non-profit research institute affiliated with an institution of higher education. For government employees, an off-duty employment application is required to be submitted and approved.

7.3.3. Income from service on an advisory committee or review panel for a federal, state, or local government, an institution of higher education, an academic teaching hospital, a medical center, or a nonprofit research institute affiliated with an institution of higher

education. For government employees, an off-duty employment application is required to be submitted and approved.

7.3.4. Income from investment vehicles, such as mutual funds or retirement accounts, as long as the covered individual does not directly control the investment decisions made in those vehicles; or

7.3.5. Travel reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

7.4. Text of Documentation to be provided on request. If an individual conducting research or any 59 MDW Key Personnel discloses payments, intellectual property interests, or royalties, the individual conducting research must provide a copy of any related agreement, contract, offer letter, or other documentation on request of:

7.4.1. The Commander of the 59 MDW (59 MDW/CC);

7.4.2. COI Manager; or

7.4.3. Any other person or entity with administrative responsibility in regard to reviewing financial interest disclosure statements or approving a related management plan [e.g., Authorized Institutional Official (AIO), SES Chair].

7.5. Disclosure Forms.

7.5.1. 59 MDW Form 14, *Financial Conflict of Interest Disclosure for Researchers* is the primary vehicle used by individuals conducting research.

7.5.2. 59 MDW Form 15, *Financial Conflict of Interest Disclosure for 59 MDW Key Persons and Reviewers* will be used for Individuals who have authority to review, approve or oversee research.

8. When to Disclose.

8.1. All individuals conducting research involving human subjects will indicate on the protocol template, whether or not they have, or may be perceived to have, a potential FCOI. If a researcher indicates that they may have a conflict, they will complete a 59 MDW Form 14 and send the form via email directly to the COI Manager for review and potential forwarding to the SES for a determination.

8.2. The disclosure status of research personnel will be evaluated upon changes to a researcher/research team member's financial circumstances and during the continuing review of research at intervals appropriate to the degree of risk, but not less than once per year, as determined by the IRB.

8.3. In the event that an individual conducting research is also an executive at the 59 MDW, they also must annually disclose financial interests to the AF Office of General Council within the OGE Form 450, *Confidential Financial Disclosure Report – Executive Branch* and submit 59 MDW Form 14 to the COI Manager. The OGE Form 450 is a separate process that does not overlap with the research COI process.

8.4. Individuals conducting research who are planning to participate in a U.S. Department of Health and Human Services (DHHS)-funded research project will submit a financial interest

disclosure statement to DHHS no later than the time of application for DHHS-funded research, except that an individual who is new to the 59 MDW and who is planning to participate in an on-going DHHS-funded research project will submit the statement no later than the 30th day of initial employment.

8.5. 59 MDW Key Personnel will complete a 59 MDW Form 15 upon appointment to their position and send the form via email directly to the COI Manager for review and potential forwarding to the SES for a determination.

9. Disclosure Process for Researchers.

9.1. A Principal Investigator (PI) must ensure that the IRB initial protocol application accurately indicates whether any member of the research team has a conflict to disclose. Subsequent to the approval of the initial protocol application, the PI must ensure that changes to any research team member's conflict(s) of interest are appropriately reported to the IRB as soon as discovered either as an amendment to the study or during continuing review. The IRB forms contain COI disclosure sections and are available on the 59 MDW/ST Clinical Investigations and Research Support (CIRS) Knowledge Exchange (KX) website.

9.2. For collaborative research or AF-only conducted research involving human subjects that engages 59 MDW employees and is approved by an external IRB, the COI Manager will ensure each 59 MDW investigator has completed all required 59 MDW COI documents for AIO institutional review and approval. If there is a conflict, the 59 MDW SES develops a COI Management Plan, and it must receive 59 MDW AIO approval prior to implementation.

9.2.1. For collaborative research involving 59 MDW personnel and involving human subjects that is approved by 59 MDW IRB, the COI Manager will ensure each 59 MDW investigator has completed all required 59 MDW COI documents for AIO institutional review and approval. If there is a conflict, the 59 MDW (staff or COIM) develops a COI Management Plan, and it must receive 59 MDW AIO approval prior to implementation.

9.3. If there is a potential COI, each conflicted individual will download, complete, encrypt, and email a 59 MDW Form 14 to the COI Manager. Disclosure template forms will be available on the Clinical Investigations and Research Support (CIRS) Knowledge Exchange (KX) website. The instructions for completing the disclosure are on the form.

9.3.1. The COI Manager reviews each 59 MDW Form 14 they receive for completeness and to determine whether the disclosed issue(s) meets the definition of a COI (contained in the form).

9.3.2. In general, if the answers to all of the questions on page 2 of the 59 MDW Form 14 are "No," then the researcher does not have a conflict. In this case, the individual will be notified by the COI Manager that they do not have a conflict and should revise the pending IRB documents as applicable (e.g., new protocol, progress report, or amendment).

9.3.3. If the 59 MDW Form 14 is complete and appears to indicate a conflict, the COI Manager schedules the disclosure for review by the SES. The SES will work with the PI to develop a Research Conflict Management Plan, if determined to be required.

9.3.4. The SES-approved Management Plan will be forwarded to the IRB and the PI will be notified to submit the protocol application to the IRB. The convened IRB will review the Management Plan. If the IRB requires changes to the Management Plan, it will be

returned to the COI Manager to coordinate with the SES and PI. The revised Management Plan is returned to the IRB designated reviewer for approval and reporting to the convened IRB. IRB-approved Management Plan is provided to the AIO, who has the authority to fully approve the Management Plan for implementation or request additional modifications or additional protections. The AIO can request additional restrictions/protections to the Management Plan, but cannot reduce or remove any IRB-directed restrictions or protections.

9.3.5. The COI Manager will file and track the approved COI Management Plan for future changes and annual review.

9.3.6. 59 MDW/ST will conduct annual and ad hoc audits on The Conflict of Interest Program.

9.4. The SES will meet as necessary, but at least annually. The SES reviews 59 MDW Form 14s forwarded by the COI Manager and determines whether a significant COI exists related to research involving human subjects.

9.4.1. If a COI exists, the SES will develop a Management Plan, if determined to be required, in coordination with the individual conducting research.

9.4.2. If no conflict exists, the SES will maintain records related to the review and report to the Scientific Advisory Committee (SAC) as appropriate.

9.5. The disclosure status of research personnel will be evaluated upon changes to a researcher/research team member's circumstances and during the continuing review of research at intervals appropriate to the degree of risk, but not less than once per year, as determined by the IRB.

9.6. The protocol and Management Plan is approved with/without additional IRB restrictions/protections and submitted to the AIO for review and final approval and signature.

9.6.1. The AIO can add additional restrictions/protections to the IRB-approved Management Plan but cannot reduce or remove IRB-mandated restrictions/protections.

9.7. After AIO approval, the Management Plan will be sent to the COI Manager to execute signatures, file, and update the tracking database.

9.8. The filed Management Plan (final/signed) will be kept by the COI Manager for recordkeeping and auditing purposes, and filed in the Study Regulatory Binder. Notifications will be sent to:

9.8.1. Conflicted researcher.

9.8.2. IRB.

9.9. The signed Management Plan may be accessed, if necessary, by:

9.9.1. Researcher's direct supervisor.

9.9.2. Research Monitor (if applicable).

9.9.3. Defense Health Agency (DHA).

9.9.4. 59 MDW Research Compliance Office.

9.9.5. 59 MDW IRB.

9.9.6. 59 MDW COI Manager.

9.10. Any change to the status of the conflict or any non-compliance issues with the Research Conflict Management Plan must be reported to the COI Manager and IRB within 30 days of discovery.

10. Disclosure Process for 59 MDW Key Persons and Reviewers.

10.1. Key persons and Reviewers disclose annually on a Form 15 regardless of conflict status. If the 59 MDW Form 15 indicates a conflict, the key person's conflict will be evaluated by the SES.

10.2. The SES reviews 59 MDW Form 15s forwarded by the COI Manager and determines whether a significant COI exists related to research involving human subjects.

10.3. If a COI exists, the SES will develop a Management Plan, if determined to be required, in coordination with the key person or reviewer.

10.4. If no conflict exists, the SES will maintain records related to the review and report to the Scientific Advisory Committee (SAC) as appropriate.

10.5. The disclosure status of research personnel will be evaluated upon changes to a key person's circumstances.

10.6. The Management Plan is submitted to the AIO for review and final approval and signature.

10.7. The AIO can add additional restrictions/protections to the Management Plan.

10.8. After AIO approval, the Management Plan will be sent to the COI Manager to execute signatures, file, and update the tracking database.

10.9. The filed Management Plan (final/signed) will be kept by the COI Manager for recordkeeping and auditing purposes. Notifications will be sent to:

11. Conflicted key person or Reviewer.

11.1. The signed Management Plan may be accessed, if necessary, by:

11.1.1. Key Person's direct supervisor.

11.1.2. Defense Health Agency (DHA).

11.1.3. 59 MDW Research Compliance Office.

11.1.4. 59 MDW IRB.

11.1.5. 59 MDW COI Manager.

11.2. Any change to the status of the conflict or any non-compliance issues with the Conflict Management Plan must be reported to the COI Manager and IRB within 30 days of discovery.

12. Management of Researcher Financial Conflict Of Interest (FCOI).

12.1. Management Required for a FCOI.

12.1.1. If the SES determines that individuals conducting research or Key Personnel have a FCOI, the SES, in cooperation with the covered individual, will develop a Management

Plan governing that conflict. The Research Conflict Management Plan template will be used to draft the plan.

12.1.2. If research is ongoing and a new research team member discloses a significant financial interest related to that research or any other covered individual discloses a new significant financial interest related to that research, the SES will, no later than the 60th day after the filing of the disclosure statement:

12.1.2.1. Review the disclosure statement to determine if a FCOI exists; and

12.1.2.2. If a FCOI exists, implement an interim Management Plan or implement other interim measures to ensure the objectivity of the research.

12.1.3. If the SES learns of a significant financial interest that was not timely disclosed or was not timely reviewed, they will, no later than the 60th day after learning of the interest:

12.1.3.1. Determine whether the significant financial interest is a FCOI; and

12.1.3.2. If a FCOI exists, implement an interim Management Plan or implement other interim measures to ensure the objectivity of the research going forward. The conflicted researcher/research team member may not participate in the study until a Management Plan is approved.

12.1.4. In addition, if a FCOI was not timely identified or managed, or if individuals conducting research fail to comply with a Management Plan, the SES will, no later than the 120th day after AIO determination of non-compliance:

12.1.4.1. Complete and document a retrospective review and determination as to whether research conducted during the period of non-compliance was biased in the design, conduct, or reporting of the research; and

12.1.4.2. The AIO and IRB will implement any measures necessary with regard to the individuals conducting research and those participating in the research between the date that the non-compliance is identified and the date the retrospective review is completed.

12.1.5. For DHHS-covered research projects, the retrospective review will cover key elements as specified by federal regulations and may result in updating the Financial Conflict of Interest Report described by the “Financial Conflict of Interest Report” section below, notifying the DHHS, and submitting a mitigation report as required by federal regulation.

12.2. Management Plan Design and Agreement.

12.2.1. A Management Plan may impose any condition and prescribe any action necessary to manage a FCOI, including an action reducing or eliminating the FCOI, to ensure that the design, conduct, or reporting of the research is free from bias or the appearance of bias. Examples of conditions or actions that may be recommended include:

12.2.1.1. Public disclosure of the conflict of interest in presentations and publications;

12.2.1.2. For research involving human subjects, disclosure of the conflict to research participants in the informed consent;

12.2.1.3. Appointment of an independent Research Monitor with authority to take measures to protect the design, conduct, and reporting of research against bias, or the appearance of bias, resulting from the conflict of interest;

12.2.1.4. Modification of the research plan;

12.2.1.5. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

12.2.1.6. Divestiture or reduction of the financial interest; or

12.2.1.7. Severance of relationships that create an actual or potential FCOI.

12.2.2. A Management Plan must be in the form of a written agreement and must:

12.2.2.1. Provide that the individuals conducting research acknowledges receipt of the plan and understands the requirements of this policy and the required actions and other terms of the plan, including the timeframes for required actions; and

12.2.2.2. Clearly identify each person responsible for monitoring compliance with the plan.

12.3. Monitoring and Compliance. Each person conducting, approving, or overseeing research under a Management Plan will comply fully and promptly with the plan, and each person identified in the Management Plan as having responsibility for monitoring compliance with the plan will carefully and fully monitor that compliance. The 59 MDW COI Manager will work with the conflicted researcher's supervisor to ensure Management Plan compliance. Deviations from or changes to the Management Plan will be reported to the 59 MDW IRB by the COI Manager, as soon as they are discovered.

12.4. Certification and Reports to the Food and Drug Administration and DHHS. Federal regulations require that each application for funding to the Food and Drug Administration or the DHHS include specific certifications and agreements in regard to this policy and FCOI. Federal regulations also require that the 59 MDW make the reports required by this policy for DHHS-funded research.

12.5. Financial Conflict of Interest Report to DHHS. Before the expenditure of any funds under a DHHS-funded research project, the appropriate organizational officials will make the Financial Conflict of Interest Report to the DHHS awarding component in compliance with 42 CFR 50, Subpart F, and 45 CFR 94, *Responsible Prospective Contractors*. In general, those regulations require a Financial Conflict of Interest Report regarding those interests that the 59 MDW determines are FCOI, including FCOI of sub-recipients. The reporting will include specified information sufficient to enable the awarding component to understand the nature and extent of the financial conflict and to assess the appropriateness of the Management Plan related to the COI. Federal regulations require reporting, within a specified period, of a FCOI identified subsequent to an earlier report and require annual updating of reports regarding previously disclosed FCOI.

12.6. Federal Enforcement.

12.6.1. Federal regulations, 42 CFR 50, Subpart F, and 45 CFR 94, require the 59 MDW to notify the DHHS of instances in which the failure of individuals conducting research to comply with this policy or a Management Plan appears to have biased the design, conduct,

or reporting of DHHS-funded research. The DHHS awarding component may take enforcement action or require the 59 MDW to take action appropriate to maintaining objectivity in the research. The 59 MDW must make information available to HHS or the DHHS awarding component as required by federal regulation.

12.6.2. If the DHHS determines that clinical research was funded by DHHS to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by individuals conducting research with a FCOI, that was not managed or reported by the 59 MDW, as required by federal regulation, the 59 MDW will require the individual conducting research involved to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations.

12.7. The SES will apply the following principles to determine whether an individual with a FCOI has demonstrated compelling circumstances that justify allowing that individual to conduct research involving human subjects.

12.7.1. Magnitude of Risk. The SES should determine the nature and degree of scrutiny required for any of these relationships or interests by assessing the potential for a COI and weighing the magnitude of any risk to human subjects.

12.7.2. Evaluation Criteria. When considering a request by an individual with a FCOI to conduct research involving human subjects, the circumstances that the SES should evaluate include:

12.7.2.1. The nature of the research.

12.7.2.2. The magnitude of the interest and the degree to which it is related to the research.

12.7.2.3. The extent to which the interest could be directly/substantially affected by the research.

12.7.2.4. The degree of risk to involved human subjects that is inherent in the research protocol.

12.7.2.5. The extent to which the interest is amenable to effective oversight and management.

12.7.2.6. Whether the individual is uniquely qualified by virtue of expertise and experience and the research could not otherwise be conducted as safely or effectively without that individual.

12.7.3. External Monitoring of Single/Primary Site Trials. Serving as the sole or primary performance site might be justified under compelling circumstances (e.g., when the research is an early-stage or feasibility trial and the expertise of 59 MDW investigators is essential to the research). In such a case, the SES should approve the circumstances, and if advisable, the research should be subject to monitoring by an oversight body with external members (e.g., a data and safety monitoring board).

12.7.4. Second-Level, External HQ USAF/SG Review. When the SES has determined that compelling circumstances exist, the 59 MDW AIO should consider the desirability of requesting DHA review and oversight.

12.8. Requesting a Reconsideration of Approved Management Plan.

12.8.1. Any 59 MDW personnel subject to a COI Management Plan will have the right to request reconsideration of any decision under this procedure.

12.8.2. A request for reconsideration must be submitted in writing to the SES within ten (10) working days. The request should include, at a minimum, the management clause(s) needing reconsideration, an explanation of why the approved management will not work, and a proposed revision to the approved management clause(s).

12.8.3. The SES will review the request and determine whether it has sufficient information to make a decision. If adequate detail is provided, the SES will determine whether the original approved clause(s) will stand or if a modification is approved; otherwise, additional detail will be sought from the requesting party.

12.8.4. If a modification is approved, the SES can accept the resolution proposed by the official, or adopt an alternate resolution. Regardless of the chosen resolution, the SES will provide the official with a written determination, including a justification for the chosen resolution, within fifteen (15) business days.

12.8.5. Submitted requests that impact the design or proposed conduct, performance, or analysis of research may require an IRB and/or AIO hold (including expenditures) to be placed upon the specific project in question until the management issue is resolved. If such a hold is required, the SES will communicate the need for a hold to the IRB and AIO.

12.8.6. If a consensus between the investigator and the SES cannot be reached about the Management Plan to mitigate the conflict of interest and there is no consensus with the IRB determination for the COI Management Plan, the investigator may appeal the determination to the IO/AIO and if still unresolved to DHA ORP. Even if the individual requests a higher level determination for their COI Management Plan, the higher level authorities cannot overturn the IRB determination. Refer to DHA policy for further guidance.

13. Managing Institutional Conflict Of Interest (ICOI) in Research .

13.1. The welfare of human participants and the integrity of research will not be compromised, or appear to be compromised, by competing institutional interests or obligations. Although 59 MDW/ST has separated technology transfer functions from research administration, circumstances may exist in which separation of function is not sufficient to avoid the appearance of an ICOI.

13.2. A COI occurs when any financial arrangement, situation or action affects or is perceived to exert inappropriate influence on the design, review, conduct, results, or reporting of research activities or findings. Concerns are based on the potential effects the conflicts may have on the real or perceived quality of the research and the treatment of research participants. The perception that a COI exists may not affect the actual development, management and evaluation of the study, but may negatively impact on the perceived validity of the study and the credibility of both the investigator and the institution.

13.3. Licensing, technology transfer, and patents as a source of ICOI. Unlike our civilian counterpart organizations, the 59 MDW as a DoD organization, does not hold investments or equity in private or start-up companies. The assessment of ICOI as related to licensing

technology and patents is covered in AFI 61-301, *The Domestic Technology Transfer Process and the Offices of Research and Technology Applications Cooperative Research and Development Agreements*.

13.3.1. Invention Disclosure. In the case of an invention (to include improvement of an invention) or believed invention, the Air Force inventor must complete two original AF Forms 1279, *Disclosure and Record of Invention* with the assistance of the 59 MDW/ST Office of Research and Technology Applications (ORTA). Once the AF Form 1279 is completed and signed, an AF Form 1981, *Invention Evaluation* is then prepared with the assistance of the 59 MDW/ST ORTA for submission to and approval by the consultant to the USAF Surgeon General for the medical specialty the invention is most aligned with (sign as “Evaluator” in [paragraph 14](#)). These forms are available from the 59 MDW/ST ORTA office or on the Air Force Portal for official forms, <http://www.e-publishing.af.mil>. The AF Form 1981 will then be sent to the 59 MDW/ST for review and approval. They will work with the inventors to revise the forms and supporting documents as needed, approve the package (sign as “Approving Official” in paragraph 14 of the AF Form 1981, as delegated by 59 MDW/ST to AFMC LO/JAZ for review and determination if a patent application will be pursued by the USAF. The AFMC LO/JAZ office pursues one of three outcomes for the Government as follows:

13.3.1.1. Maintains rights, title, and interest with regard to any invention of a Government employee,

13.3.1.2. Claims a royalty-free license with ownership remaining with the inventor, or

13.3.1.3. Claims no interest or license (i.e., all rights remain with the inventor). The 59 MDW/ST ORTA will track and report the status of the patent submission to the inventors and 59 MDW/ST. For patents that are approved, the 59 MDW/ST ORTA will work with Techlink to identify industry partners who are interested in licensing the patent to develop commercial products based on the invention. Inventors may be called upon to provide technical information about their invention, but must be excluded from the Patent Licensing Agreement (PLA) negotiation and approval process.

13.3.2. A CRADA is an agreement between the government and one or more non-federal parties under which the government may accept, retain, and use funds, personnel, services, facilities, equipment, or other resources from collaborating parties in order to conduct research and development in the context of a particular research project. This may often include the further development of a government invention and may be entered into cooperation conjunction with a license agreement. CRADA templates are approved maintained by AFMC LO-JAZ at the national level. Minor changes to the CRADA templates are who may negotiate minor changes by with the collaborator’s (licensee) legal counsel, investigator, 59 MDW/ST ORTA, and 59 MDW’s Servicing Legal Attorneys. Changes to the CRADA template are forwarded to AFMC LO/JAZ office for review and approval. The 59 MDW/ST ORTA office will coordinate with AFMC LO/JAZ for legal review of these requested changes. Following review and approval by LO/JAZ and the 59th Medical Wing Legal Counsel, CRADAs are signed by all parties and returned to the 59 MDW/ST ORTA for execution, distribution, maintenance, tracking, and reporting. Any CRADAs that involve research or development conducted or supported by the inventors or

relatives/associates will be referred to the COI Manager and SES. All CRADAs and other agreements are formally staffed through 59 MDW/ST ORTA prior to final signature.

13.3.3. Royalties. Royalty income to the Air Force is monitored and reported by the 59 MDW/ST ORTA office and distribution is coordinated with the Air Force Research Laboratory Patent Manager (AFRL/SB), 59 MDW/SGARB/Resource Management Office and ST. Centralized handling of royalty income allows compilation of data for evaluating and reporting on the program's effectiveness and ensures compliance with applicable laws (e.g., the current federal royalty income cap of \$150,000 per year per employee). AFRL/SB manages the payments to inventors through Defense Finance & Accounting Center.

13.3.4. Tracking. 59 MDW/ST ORTA will maintain a tracking log of invention disclosures, patents, and royalties received from any patents or inventions and provides regular updates to 59 MDW/AIO and SAC membership along with number and type of agreements established. Protocols which may be affected by income received from royalties will be flagged for discussion by the SAC regarding potential institutional COI and, if necessary, referred to the COI Manager and SES.

13.3.5. Review. The SES will review research with the potential for ICOI and determine whether the potential conflicts are managed adequately for the protection of human participants.

13.4. 59 MDW Key Personnel Conflicts as a source of ICOI. Individuals identified as being in 59 MDW Key Personnel positions must disclose financial interest annually during the month of February or within 30 days of assignment using the OGE Form 450, in addition to submitting 59 MDW Form 15 to the COI Manager.

13.4.1. The 59 MDW/COI Manager will check information about project sponsors, vendors, and gift donors to determine whether the outside entity also has other types of financial or business contractual relationships with the 59 MDW.

13.4.2. Annually (February), the COI Manager compares the 59 MDW Form 15, received from 59 MDW Key Personnel, with the list of gifts and donations related to research obtained from 59 MDW/SGARB/Resource Management Office to identify overlaps that may indicate potential conflict.

13.4.2.1. The COI Manager sends the potential conflict information to the SES. The appropriate SES members will develop a Research Conflict Management Plan, if determined to be required.

13.4.2.2. All 59 MDW Forms 15 are destroyed in accordance with Air Force Records Information Management System Records Disposition Schedule, by the COI Manager.

13.4.3. If a new conflict arises over the subsequent year before the next review, the individual in the Key Personnel position will self-report the new conflict to the COI Manager.

13.5. Management of ICOI. The SES will assess potential ICOI, and weigh the magnitude of any risk to human participants and the institution. When reviewing potential ICOI, the SES will assume an inclination against the conduct of research involving human subjects at, or under the auspices of, the institution where a COI appears to exist. However, the assumption

may be overturned when the circumstances are compelling and the SES Committee has approved an effective conflict Management Plan.

13.5.1. A key aspect of decision-making is to analyze when it would be appropriate, and in the public interest, to accept and manage a COI, rather than require that the conflict be eliminated. In some cases, the benefits of conducting a proposed research activity at the institution will be potentially high, and the risks will be low. In other cases, the scientific advantages of conducting the research may be speculative, and the risks may be great. In these latter instances, the conflict should be avoided.

13.5.2. Each case of ICOI should be evaluated based upon the nature of the science, the nature of the interest, how closely the interest is related to the research, the degree of risk that the research poses to human participants, and the degree to which the interest may affect the research.

13.5.3. Potential actions to be considered for improving the protection of participants may involve any or a combination of the following recommendations:

13.5.3.1. Disclosure of the conflict to potential participants.

13.5.3.2. Monitoring of research and compliance with management plan by independent reviewers.

13.5.3.3. Reducing or otherwise modifying the financial (equity or royalty) stake involved.

13.5.3.4. Denying the proposed research at the institution, or halting it if it has commenced (i.e., move the research to another, unconflicted institution, as needed).

13.5.3.5. Increasing the segregation of the decision-making between the institutional and the research activities.

13.5.4. If the SES determines that an institutional conflict(s) exists, the SES will work with the conflicted Institution's representative to create a COI Management Plan, if determined to be required.

13.5.5. The Management Plan is approved by the IO/AIO, and filed with the COI Manager for tracking and compliance purposes. If the ICOI involves research involving human subjects, it must be approved by the IRB before being forwarded to the IO/AIO for final approval and implementation.

13.5.6. The SES annually reviews sources of institutional conflict and develops Management Plans, as applicable and/or on an as needed basis.

LAUREN H. BYRD, Colonel, USAF, MSC
Administrator

Attachment 1**GLOSSARY OF REFERENCES AND SUPPORTING INFORMATION*****References***

- 21 CFR 54, *Financial Disclosure by Clinical Investigators*, 1 April 2018
- 21 CFR 56.107, *Institutional Review Boards*, 1 April 2018
- 32 CFR 219.107, *Protection of Human Subjects*, 1 July 2018
- 42 CFR 50 Subpart F, *Policies of General Applicability*, 17 March 2016
- 45 CFR 94, *Responsible Prospective Contractors*, 17 March 2016
- AFPD 51-5, *Administrative Law, Gifts, and Command Relationships*, 31 August 2018
- AFI 51-506, *Gifts to the Department of the Air Force from Domestic and Foreign Sources*, 16 April 2019
- AFI 61-301, *The Domestic Technology Transfer Process and the Offices of Research and Technology Application Cooperative Research and Development Agreements*, 16 September, 2019
- DoD 5500.07-R, *Joint Ethics Regulation (JER) – Change 7*, 17 November 2011
- DoDI 3216.02_AFI 40-402, *Protection of Human Subjects and Adherence to Ethical Standards in Air Force Supported Research*, 10 September 2014
- 59 MDWI 51-601, *Management of Gifts and Grants of Tangible Property*, 12 January 2016

Prescribed Forms

- 59 MDW Form 14, *Financial Conflict of Interest Disclosure*
- 59 MDW Form 15, *Financial Conflict of Interest Disclosure for 59 MDW Key Personnel and Reviewers*

Adopted Forms

- AF Form 847, *Recommendation for Change of Publication*
- AF Form 1279, *Disclosure and Record of Invention*
- AF Form 1981, *Invention Evaluation*
- OGE Form 450, *Confidential Financial Disclosure Report – Executive Branch*

Abbreviations and Acronyms

- AIO**—Authorized Institutional Official
- COI**—Conflicts of Interest
- CIRS**—Clinical Investigations and Research Support
- CRADA**—Cooperative Research and Development Agreement
- DHA**—Defense Health Agency

DHHS—Department of Health and Human Services

DoD—Department of Defense

FCOI—Financial Conflict of Interest

ICOI—Institutional Conflict of Interest

IRB—Institutional Review Board

KX—Knowledge Exchange

MDW—Medical Wing

PI—Principal Investigator

SAC—Scientific Advisory Committee

SES—Scientific Ethics Subcommittee

Terms

59 MDW Form 14, Financial Conflict of Interest Disclosure for Researchers—The primary vehicle used by individuals conducting research to disclose financial interests.

59 MDW Form 15, Financial Conflict of Interest Disclosure for 59 MDW Key Personnel and Reviewers—The primary vehicle used by individuals conducting research to disclose financial interests.

59 MDW Key Personnel—Individuals who approve or oversee research. This term includes, but is not limited to individuals serving as: 59 MDW/ST Senior Directors and Deputies; 59 MDW/ST Program Directors for Trauma and Clinical Care Research, Clinical Investigations and Research Support, Diagnostic and Therapeutics, Nursing Research, Research Quality Assurance and Education, Protocol Office; 59 MDW/ST Project Managers; Research Managers or Monitors and Chairs of the 59 MDW Human Research Protection Program (HRPP) Steering Committee, 59 MDW IRB, 59 MDW SES Committee, and other human subjects research-related committees that might be created in the future.

Conflict of Interest (COI)—Any known interest, actual or potential, financial or non-financial, of a person (or of their spouse, dependent child, family member) that could affect, or could reasonably appear to affect, their judgment. Conflicts of interest often arise from financial relationships with a research sponsor or from intellectual property rights

Cooperative Research and Development Agreement (CRADA)—An agreement between one or more federal laboratories and/or technical activities and one or more nonfederal parties. Under a CRADA, the government laboratories and/or technical activities shall provide personnel, services, facilities, equipment, or other resources with or without reimbursement (but not funds to the nonfederal parties). CRADAs are instruments that may be used in all aspects of a product and/or system life cycle where Research, Development, Testing and Evaluation (RDT&E) funded activities occur. The nonfederal parties shall provide funds, personnel, services, facilities, equipment, or other resources toward the conduct of specified research and development efforts that are consistent with the missions of the laboratory and/or technical activity. The CRADA partners shall share in the intellectual property developed under the effort. This term does not

include a procurement contract or cooperative agreement as used in 31 U.S.C. 6303, 6304, and 6305.

Financial Conflict Of Interest (FCOI)—Equity holdings in commercial sponsors, consulting fees, royalties, patent rights, honoraria, funding incentives for patient enrollment, stock options in commercial sponsors, referral or finder’s fees, nonmonetary “perks” or rewards, post-study reward (e.g., vacation trip), etc.

Financial Interest—Anything of monetary, whether or not the value is readily ascertainable.

Gifts—Anything of monetary value (e.g. cash and investments) that have a market value exceeding \$20 per source per occasion and gifts from a single source with an aggregate market value exceeding \$50 in a calendar year.

Gifts of Travel—To include lodging, transportation and food that have a market value exceeding \$20 per source per occasion and gifts from a single source with an aggregate market value exceeding \$50 in a calendar year.

Immediate Family Member—A 59 MDW Organizational Official's biological, foster, or adoptive parent, a stepparent, spouse, qualifying adult, a biological, adoptive, or foster child, a stepchild, a legal ward, or a person whom the 59 MDW Organizational Official has (or had during the person's youth) daily responsibility and financial support, “mother, father, brother, sister, son, daughter, mother-in-law, father-in-law, brother-in-law, sister-in-law, son-in-law, daughter-in-law, grandparents, and grandchildren” of both the organizational official and spouse and/or qualifying adult.

Immediate Family Member (For Financial Disclosure Purposes)—Includes: a spouse; dependent child or stepchild; any other person financially dependent on an individual conducting research; and any other person with whom the individual conducting research has joint financial interests such that an objective third party could reasonably conclude that the decisions of the individual conducting research or other exercise of professional responsibilities at the 59 MDW could be influenced by the effect of that action on the person's financial interest. **Note:** An immediate family member is without regard to whether a legal or biological family relationship exists with the individual conducting research. If the individual conducting research is in doubt, the individual should resolve the doubt in favor of disclosure.

Individual Conducting Research—An individual who, regardless of title or position, is responsible for the design, conduct, or reporting of research, including, but not limited to, a principal investigator, associate investigator, or project director.

Institutional Conflict Of Interest (ICOI)—59 MDW financial interests (i.e., licensing, technology transfer and patents or gifts) or ST Senior Management financial interests (i.e., someone who is charged with review and approval of research, oversees, or influences research) that might reasonably appear to adversely affect the integrity or objectivity of a researcher or decisions involving the 59 MDW’s primary interests or missions (e.g., research, teaching, and clinical care or administration of these missions).

Organizational Official—Persons holding leadership or administrator positions within the 59 MDW, including those holding these positions in a temporary capacity. This term includes, but is not limited to individuals serving as: 59 MDW Commander; 59 MDW Vice Commander; member of the Board of Directors; Program Directors; Group, Squadron, and Unit Commanders and their

Deputies; Flight Commanders; Element Chiefs; 59 MDW Compliance Officers; and Chairs of the 59 MDW HRPP Steering Committee and 59 MDW IRB.

Research—Any activity that is a systematic investigation, including RDT&E, designed to develop or contribute to generalizable knowledge as defined in 32 CFR 219.102(d). (DODI 3216.02, Glossary Part II).

Researcher/Research Staff—Any individual responsible for the design, conduct, and reporting of research for a given study. Research staff may or may not include the following: co-investigators, associate investigators, research coordinators/assistants, and any individuals engaged in human research.

Research Involving A Human Being As An Experimental Subject—An activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. This is a subset of research involving human subjects. This definition relates only to the application of 10 USC 980; it does not affect the application of 32 CFR 219. This definition does not include activities that are not considered research involving human subjects, activities that meet the exemption criteria at 32 CFR 219.101(b), and research project involving the collection of existing data, documents, records, or specimens from living individuals. (DODI 3216.02, Glossary Part II).

Research Involving Human Subjects—Activities that include both a systematic investigation designed to develop or contribute to generalizable knowledge AND involve a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information. Activities covered by 32 CFR 219.101(a) (including exempt research involving human subjects) and DODI 3216.02. (DODI 3216.02, Glossary Part II).

Significant Financial Interest—Is a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities: With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value; With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests. Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated

with an Institution of higher education. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the Public Health Service -funded research.

The term significant financial interest does not include the following types of financial interests—salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.