

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

**59TH MEDICAL WING INSTRUCTION
41-105**



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Health Services

**HUMAN RESEARCH PROTECTION
PROGRAM**

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This instruction implements Air Force Policy Directive 41-1, *Health Care Programs and Resources*. The 59th Medical Wing (59 MDW) now falls under the oversight of the Office of the Under Secretary of Defense for Personnel and Readiness [OUSD(P&R)] for all activities related to research involving human subjects, as defined in 32 Code of Federal Regulation (CFR) 219, *Protection of Human Subjects* and and DoDI 3216.02, *Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and-Supported Research*. The 59 MDW will comply with these regulatory requirements, plus additional regulatory guidance from the Deputy Assistant Secretary of Defense for Health, Research, Policy and Oversight [DASD(HRP&O)] Operating Instruction (OI). As an OUSD(P&R) institution, the 59 MDW has established policies and procedures to delineate the regulatory authority, purpose, principles, functions, and operations of the 59 MDW Human Research Protection Program (HRPP) and the 59 MDW Institutional Review Board (IRB), a component of the 59 MDW HRPP, for protecting the rights and welfare of human subjects in 59 MDW supported and conducted research. This instruction applies to all services and components assigned, attached, or under contract to the 59 MDW. This instruction is not applicable to 59 MDW personnel covered under the Department of Defense (DoD) Assurance for the Protection of Human Research Subjects (“DoD Assurance”) and HRPP of another DoD or OUSD(P&R) institution while conducting non-exempt research involving human subjects. This instruction does not apply to the Air National Guard or Air Force Reserve. 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 substantially modified to address dual research regulatory requirements for the protection of human subjects, as defined in 32 CFR 219, in addition to regulatory requirements as stated in the revised DoDI 3216.02 and the DASD(HRP&O) Operating Instruction. Human subjects research, approved before 21 January 2019, must follow the regulatory requirements stated in the old Common Rule, i.e., Title 32 CFR 219 [32 Code of Federal Regulations (CFR) Part 219; effective date of 1 October 2016 for pre-2018 requirements]. Human subjects research, approved on or after 21 January 2019, must follow the regulatory requirements stated in the revised Common Rule, i.e., (32 CFR 219; effective date of 21 January 2019)

1. Overview.

1.1. As an institution under the oversight of the Office of the Under Secretary of Defense for Personnel and Readiness [OUSD(P&R)] supporting and/or conducting research involving human subjects, it is the responsibility of the 59 MDW to establish, maintain, resource, monitor, evaluate, and continually improve its institutional Human Research Protection Program (HRPP) for protecting human subjects, in accordance with DoD, OUSD(P&R) and DASD(HRP&O) regulatory requirements. ([Attachment 1](#))

1.2. Research is a foundational component of the 59 MDW mission that spans across all 59 MDW institutional health care, medical education, and operational readiness platforms. The 59 MDW has established an institution-wide HRPP that is both dynamic and unified to ensure all human research activities are regulatory-compliant and conducted under the highest ethical standards and integrity for the protection and safety of human research subjects.

1.3. The ethical conduct of research is a shared responsibility requiring cooperation, collaboration, and effective communication. A seamless, interwoven relationship within the HRPP, to include organizational officials, HRPP Steering Committee members, investigators, and the 59 MDW IRB, is essential for creating an institutional culture of mutual respect and trust for a unified HRPP across the 59 MDW.

1.4. The applicability and issuance of this Instruction is not dependent upon any budget activity funding research, the security classification of the research, the location of the research in the United States or a foreign country, or whether the research is conducted or supported by a program that is not considered research for other purposes.

2. Ethical Principles for Conducting Human Research.

2.1. The 59 MDW Institutional Official (IO), Alternate Institutional Official (AIO), IRB, Office of Clinical Research Support, investigators, research staff, and other institutional personnel supporting research will ensure that all of their research-associated activities involving human subjects are guided by the ethical principles set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled, *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, also known as “The Belmont Report”.

2.2. The 59 MDW acknowledges its institutional responsibilities for protecting the rights and welfare of human research subjects. The 59 MDW recognizes the ethical principles of

respect for persons, beneficence, and justice, as stated in *The Belmont Report* and will apply these principles in all human research to satisfy these responsibilities and to demonstrate HRPP accountability, based on 32 CFR 219.101(c):

2.2.1. Respect for Persons. Individuals should be treated as autonomous agents, and persons with diminished autonomy and/or impaired decision-making ability are entitled to protection. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit (Belmont Report, Part B Respect for Persons, [paragraph 4](#)). This applies to obtaining informed consent and considering protections for privacy and confidentiality.

2.2.2. Beneficence. (1) Do no harm and (2) maximize possible benefits and minimize possible harms. This applies to weighing risks and benefits and determining a risk/benefit ratio.

2.2.3. Justice. The equitable selection of subjects and the equal treatment of all subjects and populations. Subjects shouldn't be selected based on mere convenience. Principles of fairness and equity apply.

3. Institutional Compliance with Laws, Regulations, Policies, and Guidelines.

3.1. The 59 MDW shall enact policies, and procedures (e.g., regulations, instructions, guidelines, and standard operating procedures) necessary to ensure that research involving human subjects covered under this MDWI is conducted ethically and in compliance with applicable federal, DoD, Air Force (AF), state, and local laws, regulations, and policies, including tribal law passed by the official governing body of an American Indian or Alaska Native tribe, as appropriate. The regulatory documents cited in [Attachment 1](#), will be made available for those involved in conducting or supporting human subjects research (HSR) at the 59 MDW, including other DoD or non-DoD collaborating sites for which the 59 MDW IRB is the IRB of Record.

3.2. When 59 MDW HSR is conducted and/or supported outside of the United States, it will comply with applicable federal and DoD regulatory requirements, including HSR regulations, national laws and policy requirements of the foreign country. When there is an unresolved conflict, legal counsel will be consulted, on a case-by-case basis, to determine whether host nation HSR laws are applicable, and where differences exist, the standard that is most protective of human subjects will be applied. Additional guidance and counsel can be sought from the Office of the Under Secretary of Defense for Research and Engineering ([OUSD(R&E)]), through the Director, Research Regulatory Oversight Office (R2O2).

3.3. As an OUSD(P&R) institution, the 59 MDW has a DoD Assurance for the Protection of Human Research Subjects (DoD Assurance #P60023), as issued by OUSD(P&R), which authorizes the institution to become engaged in DoD-supported or DoD-conducted non-exempt human research. Additionally, the 59 MDW has a Federal Wide Assurance (FWA) for the Protection of Human Subjects (FWA #00001750), issued through the Department of Health and Human Services (DHHS), Office of Human Research Protections (OHRP), which authorizes the institution to become engaged in DHHS-supported or conducted non-exempt human research.

3.4. Except when activities are not considered research [§219.102(l)(1-4)] or when research is exempt or not subject to the requirements of the Common Rule [§219.104(d)(1-8)], the 59

MDW DoD Assurance applies to all research involving human subjects. Only 59 MDW Designated IRB Reviewers or IRB are authorized to make determinations regarding whether or not an activity is HSR, exempt research, non-human research or not research.

3.5. When the 59 MDW becomes engaged in DHHS-funded research to which its FWA applies, the 59 MDW HRPP and its IRB component will comply with the DHHS revised Common Rule, to include additional research protections required for vulnerable populations, as stated in 45 CFR 46, *Protection of Human Subjects*, Subparts B-D and in Title 10 United States Code (USC) Section 980, *Limitation on Use of Humans as Experimental Subjects*.

3.6. When the 59 MDW becomes engaged in non-exempt human research approved on or after 21 January 2019, the 59 MDW HRPP and its IRB component must comply with the revised Common Rule, and with additional research protections required under 10 USC Section 980; 21 CFR 50, *Protection of Human Subjects*; 21 CFR 54, *Financial Disclosure*; 21 CFR 56, *Institutional Review Board*; 21 CFR 312, *Investigational New Drug Application*; 21 CFR 600, *Biological Products*; 21 CFR 812, *Investigational Device Exemptions*; DASD(HRP&O) OI; and DoDI 3216.02. Research that has been IRB-approved before 21 January 2019 will remain under the old Common Rule regulatory requirements) and DoDI 3216.02, unless the IRB has determined it is more beneficial to transition the research under the revised Common Rule. However, once a study has been transitioned, it cannot revert back to the old regulatory requirements.

3.7. OUSD(P&R) institutions shall NOT conduct duplicative regulatory or ethical reviews of research that has been previously reviewed, whether by a DoD IRB/HRPP or a non-DoD IRB/HRPP. However, each collaborating OUSD(P&R) institution may conduct an administrative review to determine local feasibility, to ensure the protocol meets any local or institution-specific requirements and regulations, and to ensure the local institution's personnel have situational awareness of research being conducted or supported by the institution.

3.8. Based on the revised Common Rule [§219.114(b)(1)], any United States institution engaged in collaborative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. Exceptions to this provision are discussed in [§219.114(b)(2)(i-ii)].

3.8.1. Based on DoDI 3216.02, Section 1.2., the 59 MDW reserves the option to use multiple IRBs for DoD or non-DoD collaborative studies, as deemed appropriate, based on the particular context of the human subject research study. However, written justification for a duplicative review must be sent to R2O2 for consideration and the 59 MDW may not proceed with the requested duplicative review without written approval from the Director, R2O2.

3.8.2. As of January 20, 2020, any ongoing cooperative study approved on or after 19 July 2018 should only have one IRB, unless it is not subject to the provision at 32 CFR 219.114. It is not appropriate for ongoing DoD-conducted or-supported cooperative studies using multiple IRBs to retroactively use a single IRB or submit exception documentation.

3.8.3. When an institution relies on a DoD IRB as the reviewing IRB, the responsibilities of the Human Research Protection Official (HRPO) described in Defense Federal

Acquisition Regulation Supplement (DFARS) 48 CFR 252.235-7004, and DoDI 3216.02, are fulfilled by the DoD IRB's review. DoD IRB approval will constitute the Human Research Protection Official (HRPO) review. As such, HRPO reviews are no longer required following a DoD IRB review.

3.9. Collaborating institutions conducting exempt research subject to the Limited IRB Review requirements [§219.103(e)], may also be subject to the single IRB review requirement for cooperative research [§219.114(a-c)].

3.10. When the 59 MDW becomes engaged in research that is supported or conducted by another DoD Component (e.g., Army, Navy, Coast Guard, and Marines), the 59 MDW and its IRB may be required to comply with policies and procedures of the other DoD Component.

3.11. When the 59 MDW collaborates with other non-DoD investigators who are not employed by an institution with an assurance (i.e., a non-assured institution), the 59 MDW may extend the applicability of its Federal and/or DoD Assurance to the collaborating investigators through the use of a DoD Individual Investigator Agreement (IIA).

3.12. Institutional Agreements for Institutional Review Board (IRB) Review (IAIRs) between OUSD(P&R) institutions and OUSD(P&R) IRBs are no longer required. Since the 59 MDW is considered an OUSD(P&R) institution, it can submit research for review by any IRB in OUSD(P&R) without any additional agreements.

3.13. When collaborating with DoD institutions, OUSD(P&R) institutions must establish IAIRs with the collaborating institutions and follow the standard procedures for DoD-conducted research.

3.14. When collaborating with a non-DoD institution, OUSD(P&R) institutions must:

3.14.1. Establish whether the IRB of Record for the study (generally based on the primary institution conducting the study) is a DoD IRB or a non-DoD IRB;

3.14.2. If the IRB of Record is a DoD IRB, establish IAIR(s) with the collaborating institution(s) and follow the standard procedures for DoD-conducted research;

3.14.3. If the IRB of Record is a non-DoD IRB, establish an IAIR with the non-DoD IRB and follow the standard procedures for DoD-conducted research relying on a non-DoD IRB.

3.15. The 59 MDW Institutional Official (IO) or Alternate IO (AIO) will establish procedures for review and approval of each HSR study before the institution becomes engaged in research involving human subjects and prior to initiation of any substantive changes thereto. The purpose of this review is to determine, on behalf of the institution and in light of local mission considerations, whether to permit the research. This review can be done before or after IRB approval, and is not part of the IRB review process. As such, the 59 MDW IO requires the following:

3.15.1. 59 MDW Group Commanders must ensure that all their research personnel have obtained 59 MDW Institutional Approval (IA) prior to engaging the 59 MDW in research involving human subjects. The 59 MDW becomes engaged in research when its employees or agents, as part of their official duties or using 59 MDW resources, obtain information or bio-specimens through intervention or interaction with a living individual

and use, study, or analyze the information or bio-specimens for research purposes; or obtain, use, study, analyze or generate identifiable private information or identifiable bio-specimens concerning a living individual for research purposes [§219.102(e)(1)]. IA authority is delegated to the 59 MDW AIO.

3.15.2. All 59 MDW personnel who engages the 59 MDW in HSR must obtain IA authorization before initiating any research activities. This requirement includes individuals with a 59 MDW IIA conducting human subject research with an external IRB-approved protocol. This requirement pertains only to 59 MDW personnel who are identified by name on the protocol (principal investigators, associate investigators, research coordinators, residents, and students in graduate health sciences education). When multiple 59 MDW personnel are named on the same study, only one person is required to submit the 59 MDW IA request.

3.15.3. For 59 MDW personnel engaged in HSR in which the 59 MDW IRB is the IRB of Record, the IA approval requirement is fulfilled when the AIO institutionally approves these studies for implementation within the institution by signing the 59 MDW IRB Meeting Minutes.

4. Institutional Roles, Responsibilities, and Authority.

4.1. Active institutional support, mutual trust, cooperation, and dedication by all 59 MDW staff members are essential foundational elements for a successful and ethical 59 MDW HRPP. It is the responsibility of all individuals covered under the 59 MDW HRPP to understand and apply their obligation to protect the rights and welfare of human research subjects.

4.2. 59 MDW Institutional Official (IO). The Commander of the 59 MDW (59 MDW/CC) is the 59 MDW IO for human subjects research. The 59 MDW/CC (IO) signs the Department of Health and Human Services (DHHS) (FWA #A00001750) and the DoD Assurance (#P60023) on behalf of the institution. As the most senior officer and IO, the 59 MDW/CC is ultimately responsible for ensuring HRPP compliance within the institution. The IO is responsible for the duties and responsibilities listed in the 59 MDW HRPP Standard Operating Procedure (SOP), DoDI 3216.02, DASD(HRP&O) OI and HRPP OI-001, *Institutional Review Board*.

4.3. 59 MDW AIO. The 59 MDW AIO is the point of contact for all daily operations of the institution's HRPP, to include open communication with OHRP, Food and Drug Administration (FDA), and other DoD and Federal agencies, as applicable, to address any issue(s) pertaining to the protection of human research subjects. The AIO is responsible for the duties listed in the 59 MDW HRPP SOP, OASD(HRP&O) OI and HRPP OI-001, *Institutional Review Board*.

4.4. An Authorized AIO (AAIO) has been appointed by the 59 MDW IO to assist the AIO and provide oversight and approval of specific research studies in cases where the AIO is unable to perform AIO duties due to a potential conflict of interest.

4.5. The 59 MDW Clinical Research Administrator (CRA)/Human Protections Administrator (HPA). Directs all aspects of the 59 MDW Human Research Protections Program (HRPP), in support of Graduate Medical Education (GME), medical readiness training and clinical investigations research. Formulates technical, administrative and compliance policies and

procedures to ensure the 59 MDW HRPP and all human research activities performed under the oversight of the 59 MDW IRB are regulatory compliant with all 59 MDW, Air Force, DoD and Federal laws, regulations and instructions. Oversees day-to-day clinical research operations. Interprets and implements regulations, guidance, and policies issued by higher government authorities that apply to clinical research and to the protection of human research subjects. Serves as primary point of contact for GME residents and 59 MDW staff engaged in human research. Serves as the institution's HPA subject matter expert on the HRPP and assists the AIO in managing the HRPP operation on behalf of the IO. Supervises all ongoing approval and concurrence actions from OUSD(P&R) and R2O2. Responsible for overseeing the establishment of 59 MDW research collaborations and affiliations with other civilian and DoD research institutions that may benefit the AF mission. Serves as executive staff member on the 59 MDW HRPP Steering Committee and IRB Facilitator and voting member of the 59 MDW IRB.

4.6. 59 MDW Institutional Review Board (IRB). A component of the HRPP, the 59 MDW IRB is an independent and autonomous board that provides initial and continuing review and approval for all research/clinical investigations involving human subjects, conducted by the 59 MDW or other DoD or non-DoD institutions for which it is the IRB of Record, regardless of location or funding source. The exception to this regulatory oversight would be for those protocols that meet the criteria for exemption, as outlined in the old Common Rule [32 CFR 219.101(b)(1-6)], the revised Common Rule [§219.104(d)(1, 4-6)] and 21 CFR 56.104.

4.7. The IRB also acts as the 59 MDW Research Privacy Board responsible for reviewing and approving Health Insurance Portability and Accountability Act (HIPAA) Authorizations and HIPAA Waiver requests for research involving human subjects. The IRB will assess whether study provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of the data [§219.111(a)(7)(i)]. IRB decisions are made on the following, but are not limited to: initial study reviews; amendments; progress reports; reports of Unanticipated Problems Involving Risk to Subjects or Others (UPIRSOs); protocol deviations; and substantive complaints from study participants. IRB responsibilities and duties are carried out IAW Federal, DoD, AF, state, and local regulations and policies (see [Attachment 1](#)). 59 MDW HRPP SOP, OASD(HRP&O) OI; 32 CFR 219; and HRPP OI-001.

4.7.1. Non-exempt human research may not start without approval from the 59 MDW IRB, as the designated IRB of Record. The IRB has the authority to:

4.7.1.1. Approve require modifications in (to secure approval), or disapprove, all research activities covered by §219.109(a).

4.7.1.2. Require that key information must be given at the beginning of an informed consent document [§219.117(b)(2)] before other information is given to subjects as part of informed consent [§219.116(a)(5)(i)].

4.7.1.3. Require documentation of informed consent, written or in electronic format [§219.117(a)] or may waive documentation based on [§219.116(e-g) and [219.117(c)(i-iii)], with the exception as stated in 10 United States Code (USC) Section 980. The informed consent requirements are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional

information to be disclosed in order for informed consent to be legally effective [§219.116(i)].

4.7.1.4. Notify investigators and the institution in writing of its decision to approve or disapprove a proposed research activity or of modifications required to secure IRB approval of a research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

4.7.1.5. Conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year [§219.109(e-f)]. The IRB has the authority to waive continuing review under certain circumstances, as described in §219.109(f). Although the IRB will no longer have regulatory oversight of the study, the 59 MDW will still require institutional oversight of the study through an “Institutional Extension”. If an Institutional Extension is disapproved by the AIO, the 59 MDW IRB will resume the regulatory requirement to conduct continuing reviews of the principal investigator’s (PI)’s research.

4.7.1.6. Conduct expedited review of research based on [§219.110(i-iii)].

4.7.1.7. Suspend and/or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

4.7.1.8. Make determinations on whether activities are not research, are exempt research, or are research requiring IRB approval in accordance with the 59 MDW HRPP SOP (Ref. 1), DoDI 3216.02 (Ref. bb), OASD(HRP&O) OI (Ref. x) and 32 CFR 219. [Note: The 59 MDW IRB will not consider exempt categories 7 and 8, based on the revised Common Rule that requires both Limited IRB Review and Broad Consent. These two categories of research will be accepted only as non-exempt human research studies under the regulatory oversight of the 59 MDW IRB.]

4.7.2. All decisions of the 59 MDW IRB, in accordance with this HRPP policy and procedures shall be accepted as binding conditions in order to proceed with research involving human subjects. An official or institutional entity cannot approve research that has been disapproved by the IRB (e.g., an IRB disapproval of a protocol cannot be overturned).

4.7.3. The research that has been approved by the IRB must also be approved by the IO/AIO for the institution (i.e., Institutional Authorization). The IO/AIO may approve, disapprove, or require additional safeguards to secure approval, or refer the protocol to R2O2 for a regulatory compliance determination. The IO/AIO may not reduce the IRB-approved safeguards or conditions and may not approve research that has not been approved by the IRB.

4.7.4. The 59 MDW IRB also has the additional authority to:

4.7.4.1. Make determinations on allegations or reports of non-compliance, including serious and continuing non-compliance, with 59 MDW research policies or Federal,

DoD, or AF research regulations for the protection of human subjects. Where corrective action is needed, the IRB may take appropriate actions such as, requiring study or informed consent modifications, determining data collected cannot be used for publication, suspending or terminating IRB approval, requiring additional investigator education, disqualifying investigators from conducting research involving human subjects at the institution, and/or recommending to the institution's IO/AIO that further administrative action be taken. The IRB's action shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head. The IRB will not make determinations of research misconduct.

4.7.4.2. Make determinations on allegations or reports of Adverse Events, Serious Adverse Events, Unanticipated Adverse Device Effects, and UPIRSOs. Where corrective action is needed, the IRB may take appropriate actions such as, requiring study or informed consent modifications, determining data collected cannot be used for publication, suspending or terminating IRB approval, requiring additional investigator education, disqualifying investigators from conducting human research at the institution, and/or recommending to the IO/AIO that further administrative action be taken. Any such determination shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, the department or agency head, and other Federal agencies, as required. Certain findings are reported to R2O2 to ensure documentation of oversight of IRB determinations.

4.7.4.3. Ensuring appropriate scientific and technical reviews, including reviews of Investigational New Drug (IND) use, Investigational Device Exemptions (IDE), Exempt IDE use, Abbreviated IDE use, and Off-Label use of FDA-approved drugs and devices are conducted, as needed.

4.7.4.4. Ensuring appropriate ethics reviews; HIPAA privacy and confidentiality of data reviews; legal reviews; Data Use Agreement reviews; De-Identified Data Use Agreement reviews; survey and questionnaire reviews; and Cooperative Research and Development Agreement (CRADA) reviews and gifts/grants (source, amount, and approval letter) have been conducted, as needed.

4.7.4.5. Serve as the Air Force Medical Service (AFMS) Continental United States (CONUS)/Outside CONUS (OCONUS) IRB of Record for clinical investigations and research involving human subjects for AF Medical Treatment Facilities (MTFs) not under the oversight of OUSD(P&R), who lack an internal IRB and who seek an IAIR with the 59 MDW IRB.

4.7.4.6. Review and provide input into HRPP OIs.

4.7.5. New members and alternates to the 59 MDW IRB will receive orientation to their duties. All members must have a current certificate of training from the Collaborative Institutional Training Initiative (CITI). CITI training can be accomplished on the CITI website at <http://www.citiprogram.org>. Re-current CITI training is every 3 years.

4.7.6. Research Monitor. For research involving greater-than-minimal risk to subjects, the 59 MDW IRB, as the IRB of Record, shall approve a Research Monitor (by name)

who shall have the authority to temporarily suspend a research protocol in progress, remove individual subjects from a protocol, and take whatever steps are necessary to protect the safety and well-being of research subjects until the IRB can assess the Research Monitor's report. During collaborative research, the 59 MDW IRB has the authority to appoint a local Research Monitor, even if it is relying on another DoD or non-DoD IRB as the IRB of Record for the research effort.

4.8. 59 MDW Leadership. All 59 MDW leadership (e.g., Commanders, Directors, Division Chiefs, etc.) are responsible for the ethical and legal conduct of any research involving human subjects performed by their respective staff or Graduate Health and Science Education (GHSE) program students, including any resultant research publications or presentations submitted for approval. The department heads are responsible for attesting to: the soundness of the design of research protocols; the competency of the investigator(s) to conduct the project; and the presence of sufficient resources required for the research and for protecting research participant safety. Processes to support these assurances may include internal review committees or specialized review criteria within departments. If the PI fails to meet their responsibilities, the department head is the point of contact for correction of deficiencies.

4.9. 59 MDW PIs. Principal Investigators (PIs) have the primary responsibility to safeguard the rights and welfare of each research subject. The PI will ensure compliance with applicable policies and procedures relating to the protection of human subjects and determinations of the 59 MDW IRB. The PI will also ensure that no undue influence will be asserted by any research team member towards any review or oversight committee, IRB member, or individuals involved with the 59 MDW HRPP. The PI will ensure the protocol final report is entered in the Defense Technical Information Center (DTIC) for public release.

4.9.1. For research deemed exempt from continuing review by the 59 MDW IRB or Designated IRB Reviewer, the PI must contact the Office of Clinical Research Support to request an "Institutional Extension" of their study through the 59 MDW AIO. Extensions are approved in 3-year increments and annual PI status updates must be provided to the Office of Clinical Research Support for AIO review. When the extension period has ended, the PI may contact the Office of Clinical Research Support to request another extension or close their study and HRPP OI-001.

4.9.2. Research Participant Requests for Information. The PI and members of the research staff are required to respond promptly and adequately to all requests for information received from study participants, prospective participants, and their family members or designated representatives. Research personnel must also inform participants of how to contact the IRB if they have any questions about their rights as research subjects.

4.9.3. Research Participant Complaints. The PI is expected to investigate and respond promptly to complaints and to report complaints to the IRB. Complaints that are not resolved promptly by the PI or a member of the research staff must be reported to the IRB.

4.9.4. If the PI also holds an IND or IDE as a Sponsor-Investigator, the additional responsibilities in overseeing the research normally assumed by sponsors in industry-sponsored projects will apply to the PI.

4.9.5. The PI is responsible for registering all “applicable clinical trials” on the clinicaltrials.gov registry and posting a current clinical trial consent form template for the study on a publicly available Federal web site that will be established as a repository for such informed consent forms IAW §219.116(h)(1-3).

4.9.6. The PI is responsible for the handling and storage of all investigational devices approved for use in device studies involving human subjects.

4.9.7. Research Investigator Questions, Comments, and Complaints. Research staff members and/or assigned personnel at the 59 MDW are encouraged to ask questions, provide process or research-related suggestions, and submit complaints to the Office of Research Protocol Support, IRB Clinical Research Administrator, IRB Chair, and/or the IO/AIO, as appropriate.

4.10. When collaborating with outside organizations who are sponsoring research involving human subjects (sponsors), the 59 MDW will ensure that contract or funding agreements:

4.10.1. Clearly state who is responsible for medical care and costs, during the duration of the study, for research-related injuries resulting from Greater than Minimal Risk research, as required [§219.116(b)(6)].

4.10.2. When the sponsor is responsible for monitoring the research (e.g., overseeing the progress), the sponsor or its agents should promptly report, within 7 business days, findings of serious or continuing non-compliance detected during the monitoring process that could affect the safety of participants or influence the conduct of the study.

4.10.3. Clearly state that when the sponsor is responsible for data and safety monitoring, the sponsor or its agents provide data and safety monitoring reports, including significant findings, within 60 days of study closure, unless reporting is governed by FDA or National Institutes of Health (NIH) regulatory requirements for clinical trials, in which sponsor reporting could be 1-2 years.

4.11. The Contracting Office in coordination with the PI will ensure the following language is included in the statement of work or work plan sections of all non-DoD sponsored research agreements (e.g. Contracts, CRADAs) for Greater than Minimal Risk research:

4.11.1. The sponsor will provide payment to the institution for reasonable, unreimbursed medical expenses, including hospitalization, which the institution may incur as a direct result of the treatment of a subject's injuries that directly result from the study drug or device or their administration during the clinical trial, as determined by the sponsor and the principal investigator.

4.11.2. The sponsor shall be responsible for payment of the actual and reasonable medical expenses incurred in diagnosing and treating any injury, illness, or adverse reaction of a study subject that results from the administration of the study drug or device in accordance with the protocol or the proper performance of any protocol procedure.

4.11.3. During and for a period of at least three years after the completion of the study, the sponsor shall promptly, report, within 7 business days, to the investigator and IRB any information that could directly affect the health or safety of past or current study subjects or influence the conduct of the study, including but not limited to the study results and information in site monitoring reports and data safety monitoring committee

reports as required by the protocol. In each case, the investigator and the organization should communicate any relevant findings to each study subject.

4.12. The 59 MDW Scientific Advisory Committee (SAC). The Scientific Advisory Committee (SAC) operates to align research priorities within the 59 MDW and San Antonio Medical Health System (SAMHS) with Air Force Medical Service (AFMS) and tri-Service (“Joint”) DoD requirements. This advisory body provides leadership on academic and research endeavors in order to align and advise on competing priorities. In addition, it may consider medical modernization management and resourcing challenges that affect the 59 MDW and AF Medical Service’s use of biomedical and scientific knowledge, technology development and advances in clinical and translational research. The SAC has two subcommittees: 59 MDW HRPP Steering Committee and the Scientific Ethics Subcommittee. The 59 MDW SAC reports Steering Committee and Ethics Subcommittee activities for the appropriate organizational reviews.

4.13. 59 MDW HRPP Steering Committee. The HRPP Steering Committee is comprised of 59 MDW institutional components, DoD, and non-DoD (e.g., contractors) affiliated institutional representatives. The committee is charged with establishing procedures to integrate the 59 MDW HRPP institution-wide and to ensure the HRPP is maintained in accordance with, Federal, state, and local regulations, policies, and procedures. Committee meeting minutes are submitted to the 59 MDW Scientific Advisory Committee and then forwarded to the 59 MDW Board of Directors. Minutes represent feedback, comments, information, data, and action items discussed in the meeting. The committee also generates a “State of the HRPP” annual report for presentation to the IO/AIO that integrates quarterly programmatic assessments.

4.14. 59 MDW Scientific Ethics Subcommittee. The Scientific Ethics Subcommittee (SES), a component of the Scientific Advisory Committee, is responsible for reviewing research-related Conflict of Interest (COI) including individual investigator and institutional conflicts. The SES acts as the COI Committee for the 59 MDW. The COI Manager, staffed by the 59 MDW/ST, receives disclosure forms from researchers/research staff and reviews them for significant financial interest disclosures and other non-financial sources of potential bias, such as outside positions, conflicts of commitment and conflicts of conscience. If a disclosure meets the threshold for reporting, the form will be forwarded to the SES for determination. If the SES determines that a conflict(s) exists, the SES will work with the conflicted researcher to create a COI Management Plan. The Management Plan is approved by the IRB and IO/AIO, and filed with the COI Manager for tracking and compliance purposes. In addition, the SES annually reviews sources of institutional conflict and develops management plans as applicable.

4.15. 59 MDW Office of the Chief Scientist. The Chief Scientist provides senior leadership and develops high-level collaboration among multiple entities including but not limited to AF, DoD, local, national and international governments, academic centers, industry, and development, test, evaluation and acquisition organizations. The Chief Scientist oversees and manages research activities of investigators at enterprise sites: 59 MDW, San Antonio Military Medical Center (SAMMC), San Antonio Military Health System (SAMHS), DoD partners at the Battlefield Health and Trauma Research Institute, Tri-Service Research Laboratory, Joint Base San Antonio facilities, San Antonio Uniformed Services Health Education Consortium, Uniformed Services University of the Health Sciences, and local

universities to meet organizational needs. These enterprises help leverage medical research activities being funded by Congress as directed in the National Defense Authorization Act and meet the Secretary of Defense's mandate to develop tailored Research and Development investments. The 59 MDW Science and Technology, Office of the Chief Scientist (59 MDW/ST) supports commercialization, technology transfer activities (e.g., CRADAs), and provides centralized scientific and technical expertise, resources, project management, research, and regulatory expertise to enable advancement of medical modernization to address mission capability gaps through the application of assistance, and direction and oversight to advance medical modernization through research. Knowledge gained from clinical studies and translational research is applied to create better health outcomes, improve readiness, enhance patient care, and advance capabilities globally across the Military Health System. The 59 MDW/ST provides 59 MDW staff and other AF, DoD and non-DoD affiliated collaborative institutions (e.g., DoD Services, universities, civilian research organizations, etc.) expertise to enable/assist with performance of institutional, national, and international research that address Service and DoD-specific scientific needs, AFMS top priorities, and warfighter and military beneficiary care mission capability gaps (e.g., as defined by Major Commands/Combatant Commands and Combat Support Agencies). The 59 MDW/ST also provides training and education using online and printed sources on topics related to HRPP and Institutional and Investigator Conflict of Interest (COI), the 59 MDW Research Resource Guide, and a number of educational pamphlets.

4.16. 59 MDW Clinical Investigations and Research Support Division, Office of the Chief Scientist. The 59 MDW Clinical Investigations and Research Support Division (59 MDW/STC), a subdivision of the 59 MDW/ST, supports Major Command-funded research, research involving human subjects, Graduate Health and Sciences Education (GHSE) scholarly activities, training of personnel involved in human subjects research, and the 59 MDW IRB through its Clinical Investigation Program (CIP), which is funded by Defense Health Program operation and maintenance appropriated funds. Through the CIP, 59 MDW/STC supports clinical investigation research for 59 MDW and SAMMC, SAMHS-assigned AF healthcare providers for the advancement and application of medical science for military and DoD beneficiary patient care. 59 MDW/STC also supports operational health readiness training for GHSE students and other allied health programs.

4.17. 59 MDW Office of Clinical Research Support. The 59 MDW Office of Clinical Research Support (59 MDW/STCS) provides regulatory oversight, subject protection, and affirms regulatory compliance for all clinical investigations conducted at the 59 MDW and other relying Air Force facilities. The office houses the human subjects research protocol support staff and assists investigators with protocol development, study approval, biostatistics, and dissemination of study findings.

4.18. 59 MDW Compliance Office. The 59 MDW Compliance Office, a staff function of 59 MDW/STC, is responsible for developing and implementing a Research Compliance Program providing oversight and post-approval monitoring of human research through systematic audits. The Compliance Office maintains oversight to ensure adequacy of communication with applicable committees, persons, and officials, documentation and reporting requirements of the auditing program, and adherence to timeframes for reporting and timelines for corrective actions required by the 59 MDW IRB.

4.19. Conflict of Interest (COI) Program Manager. The COI Manager manages the 59 MDW COI program on behalf of the AIO (Chief Scientist). The COI Manager ensures each 59 MDW investigator has completed all required 59 MDW COI documents for AIO institutional review and approval. The COI Manager reviews each 59 MDW Form 14, *Financial Conflict of Interest Disclosure* and 59 MDW Form 15, *Financial Conflict of Interest Disclosure for 59 MDW Key Personnel* received for completeness and to determine whether the disclosed issue(s) meets the definition of a COI (contained in the form). The COI Manager schedules the disclosure for review by the Scientific Ethics Subcommittee (see below). The 59 MDW COI Manager works with the conflicted researcher's supervisor to ensure COI Management Plan compliance and is the point of contact for reporting of deviations from or changes to the Management Plan. The COI Manager also monitors Institutional conflicts by annually reviewing gifts and grants, and comparing with funded projects.

4.20. 59 MDW Office of Public Affairs Oversight of Publications and Presentations. The AF is interested in fully informing the public about Air Force medical research activities. However, before such information is released to the public, it must be accounted for, reviewed, and cleared for security and consistency with Air Force, DoD, and federal policies. The 59 MDW Office of Public Affairs provides security and policy reviews of all proposed publications, abstracts, and presentations for publication or dissemination in any public medium (e.g., public-facing HRPP webpage and HRPP "Tips of the Week" email bulletin announcements). These reviews facilitate coordination with other agencies (502 ISG/JAC, Air Education Training Command, Air Force Surgeon General's Office, etc.), as required. The 59 MDW/STC maintains a computer database of all health sciences and medical research publications, posters, and oral presentations cleared for public release.

4.21. 59 MDW Privacy Officer. The 59 MDW Privacy Officer ensures that approved research meets the HIPAA Privacy Rule and other regulatory requirements to protect the privacy of individually identifiable health information. The Privacy Officer can review each research protocol that is submitted to the 59 MDW IRB to ensure that legal authority exists prior to the use of Protected Health Information (PHI) and Personal Identifying Information (PII) for research and to ensure that legal authority exists prior to the disclosure of PHI/PII to outside entities for research purposes.

4.22. Air Force Legal Operations Agency Medical Law Consultant (AFLOA MLC). Medical Legal Consultants advise the 59 MDW Commander and staff on all medical-legal matters. When a question arises on the applicability of certain Federal, DoD, AF, and/or other research regulations and guidance, the Medical Legal Consultants are consulted. The AF Legal Operations Agency/Claims and Tort Litigation Division (AFLOA/JACC) and the Medical Law Branch ensures the AF has a cadre of trained personnel ready to provide medical law advice and support to medical centers, hospitals, and clinics, and to manage medical malpractice claims and litigation.

4.23. 59 MDW/ST Office of Research and Technology Applications. Technology transfer is the exchange of knowledge, expertise, facilities, equipment, personnel, methods, technical information, and/or intellectual property. The 59 MDW/ST Office of Research and Technology Applications (ORTA) prepares application assessments for selected research and development projects in which a Federal laboratory is engaged and which, in the opinion of the laboratory, may have potential commercial applications. ORTA provides and

disseminates information on Federally-owned or originated products, processes, and services having potential application to state and local governments and to private industry. ORTA cooperates with and assists the National Technical Information Service, the Federal Laboratory Consortium for Technology Transfer, and other organizations which link the research and development resources of that laboratory and the Federal Government as a whole to potential users in state and local government and private industry. ORTA participates, where feasible, in regional, state, and local programs designed to facilitate or stimulate the transfer of technology for the benefit of the region, state, or local jurisdiction in which the Federal laboratory is located. ORTA is the focal point for clinical research technology transfer. ORTA supports translation of clinical research into practice, facilitates clinical researchers' collaborations with industry and academia, and enables AFMS PIs to reap benefits from research investments.

4.24. 59 MDW Information Security Office. The 59 MDW Information Security Office ensures that all identifiable research data containing PHI/PII are collected, handled, and stored in a secure manner, as required by Federal, DoD, and AF regulations. Examples of how data are safeguarded include providing and managing secured shared server folders for recordkeeping purposes (accessible only through specific computer permissions and Common Access Card (CAC) access, and by maintaining a CAC-accessible-only email server with options for marking emails for PII and For Official Use Only information with the added option for further encryption.

4.25. 59 MDSG Pharmacy Flight. The 59 MDW Pharmacy Flight is responsible for implementation and monitoring of HRPP requirements associated with the use of investigational drugs. The pharmacy is involved in all phases of investigational drug studies from planning through completion (e.g., receipt of drugs, storage, formulating, dispensing, etc.), and affords researchers adequate resources to support research studies. The pharmacy is the sole dispensary and storage location for all investigational drugs. Any issues or problems related to the safety and welfare of research subjects is reported IAW 21 CFR 312, 21 CFR 600 and 59 MDWI 44-115, *Pharmacy and Medication Management*.

4.26. 59 MDW Radiation Safety Committee. Research involving the use of radioactive substances or radiation must be approved by the Radiation Safety Committee (RSC) prior to IRB approval, IAW radiation protection standards and regulations. The RSC provides oversight of sources of radiation not covered by AFMAN 40-201, *Radioactive Materials (RAM) Management*, or AFI 91-108, *Air Force Nuclear Weapons Intrinsic Radiation and 91(B), Radioactive Material Safety Program*. The RSC priorities are: to ensure sources of radiation are operated in accordance with federal guidelines and AFIs; to review and approve research protocols using ionizing radiation; and to monitor status of internal and external inspections. The RSC reports its determinations on research involving the use of radiation and immediately notifies the PI, the IRB, IO/AIO, and the IRB Chair of possible non-compliance with their determinations.

5. Maintenance of Ethical Research Conduct.

5.1. The IO/AIO will establish policies and procedures to foster integrity and comply with ethical standards in all human research activities IAW applicable laws and regulations.

5.2. Any individual, assigned personnel, patients, visitors or organizations involved in research at the 59 MDW may submit a written or verbal allegation of non-compliance, undue

influence, coercion, etc. Such submissions may be made to the IO/AIO, IRB Clinical Research Administrator, and/or the IRB Chair.

5.3. A climate free of fear of sanction is required to foster appropriate reporting and ensure a fair review of allegations. The 59 MDW shall take steps to protect individuals who make good faith allegations and their identities shall remain confidential to the extent possible. Retaliation against good faith “whistleblowers” is illegal and will not be tolerated. The IO/AIO shall address to all allegations of non-compliance, research misconduct, acts of intimidation, undue influence, coercion, and/or retaliation associated with human research protection requirements and the administration of IRB regulatory oversight of research involving human subjects. To ensure these issues are promptly reviewed and resolved (e.g., corrective action plan), an IO/AIO-appointed investigation officer will be assigned to investigate all allegations.

5.3.1. In the event there is Institutional undue influence or coercion, R2O2 should be contacted.

5.3.2. Following the results of an investigation, only the IO/AIO has the final authority to make the determination that an allegation has been validated and will take the necessary administrative and/or Uniform Code of Military Justice corrective actions against the violator.

5.3.3. R2O2 may be notified if the HRPP staff member believes that appropriate action has not been taken by the IO/AIO to address the respective allegation.

5.3.4. If an investigation determines that an allegation is valid, the IO/AIO shall promptly report the findings to the IRB no later than 48 hours after the determination, including the FDA, DHHS, other institutional commanders, and related funding agencies, as applicable.

6. Research Conducted Under the 59 MDW HRPP.

6.1. The 59 MDW HRPP covers all human subject research conducted by 59 MDW personnel and research determined to fall under the 59 MDW DoD Assurance:

6.1.1. Biomedical research.

6.1.2. Social and behavioral research.

6.1.3. Clinical investigation research.

6.1.4. Cancer clinical trials.

6.1.5. Clinical data research.

6.1.6. Data/tissue repository research.

6.1.7. FDA-regulated research (i.e., IND and IDE studies)

7. Research Not Conducted Under the 59 MDW HRPP.

7.1. Even if research activities meet the definition for research involving human subjects, not all categories of research are permitted under the 59 MDW HRPP.

7.2. The 59 MDW HRPP does not permit the conduct of the following categories of research,

- 7.2.1. Classified research.
- 7.2.2. Prisoner or detainee research.
- 7.2.3. Research conducted in a foreign country.
- 7.2.4. Fetal research.
- 7.2.5. Research involving biological or chemical warfare agents or weapons.
- 7.2.6. Research involving large scale genomic data collected from DoD-affiliated personnel

7.3. The 59 MDW IRB will not consider exempt categories 7 and 8, based on the revised Common Rule [.104(d)(7) & (8)], that requires both Limited IRB Review and Broad Consent.

8. Activities That May or May Not be Human Research.

8.1. The 59 MDW does not have Exempt Determination Officials (EDOs). Therefore, only the 59 MDW IRB or its Designated IRB Reviewers can make official research determinations regarding whether activities are not research involving human subjects, exempt research involving human subjects, or research involving human subjects that requires IRB approval prior to its initiation.

8.2. The revised Common Rule [§219.102(l)(1-4)], lists activities that are deemed to be “not research”. In the revised DoDI 3216.02, Section G.2, Definitions, it lists activities that will not require an official determination, if they are conducted *exactly as characterized*, and the data/specimens from the activity will not be used in any way other than to support the primary aim identified in each activity’s definition.

9. Education and Training.

9.1. All OUSD(P&R) personnel at the 59 MDW, who conduct, review or approve human subject research, must receive initial and continuing education and training in the protection of human subjects commensurate with their duties and responsibilities (i.e., role-based training). The 59 MDW/ST provides online training and education topics covering HRPP and 59 MDW Institutional/Investigator COI. The HRPP and COI training are tracked by the Office of the Chief Scientist.

9.2. The 59 MDW Office of Clinical Research Support will accept on a case-by-case basis, any engaged DoD or non-DoD institution’s HRPP training certificate documenting compliance with the Minimum Education Requirements Framework compliance/training requirements set forth by OUSD(P&R). If an individual acts in more than one role with respect to human subject research, the individual is required to take the training course appropriate to each role in which they act.

9.3. Each PI who submits a human research protocol for review by the 59 MDW IRB is required to complete the University of Miami web-based CITI program in human subjects protection. All research team members listed on the protocol and research monitors (if required) must also complete CITI training. Documentation of CITI training must be received before final IRB approval is granted for the study. Completion of CITI training allows the IRB to validate that investigators possess the necessary knowledge required to conduct research.

9.4. R2O2 has established computer-based training for the protection of human subjects via the role-based CITI training course that can be accessed and completed at: <http://www.citiprogram.org/>. The 59 MDW Office of Clinical Research Support may be contacted for additional assistance.

9.4.1. All OUSD(P&R) personnel are responsible for maintaining current records of all completed research-related training and providing documentation of the training upon request.

9.4.2. A passing score of 80 percent for each module and an overall passing score of 80 percent for the entire course is required. The CITI course transcript should be downloaded by the trainee and retained. The PI must inform the Office of Clinical Research Support that the CITI training has been completed for all research staff.

9.4.3. CITI training is valid for 3 years from the initial training date and must be renewed by taking the CITI Refresher Course. If an investigator's CITI training expires, they must be removed from the research study until the training is re-accomplished. If the PI's CITI training expires, the 59 MDW IRB may make a determination to place the research on HOLD (i.e., all research activities must stop) until the PI re-accomplishes the training. The 59 MDW IRB may not approve a Continuing Review Report or amendment to a study if the PI's training is not current. If a request is made to change the PI, the 59 MDW IRB may not approve the change if the new PI does not have current CITI training.

9.4.4. For FDA-regulated research, the PI is required to complete Good Clinical Practice (GCP) training on the CITI training website every three (3) years. Completion of GCP training is recommended for other research team members. The passing score is 80 percent. The PI must inform the Office of Clinical Research Support that the GCP training has been completed for verification purposes during administrative review.

9.5. COI training is required initially upon protocol submission and every four (4) years for anyone who is responsible for the design, conduct, or reporting of research involving human subjects at the 59 MDW. Significant financial interests related to the research must be disclosed at least annually. Details on COI training requirements are outlined in 59 MDWI 51-501, *Managing Conflict of Interest in Research*.

10. Research Records Retention.

10.1. OUSD(P&R) institutions and research investigators are required to document and maintain records of their research activities.

10. 2. Research records should be maintained and protected from disposition after study closure for the timelines indicated below:

10.2.1. Research records are required to be kept for at least 3 years after the completion of the research.

10.2.2. Research records that contain protected health information that may be covered by the Health Insurance Portability and Accountability Act are required to be kept for at least 6 years after study closure.

10.2.3. Other Federal regulations may require research records to be kept for longer than the timelines specified above, i.e., FDA, DHHS, NIH, etc.

11. Continuity of Operations Strategy.

11.1. OUSD(P&R) institutions are required to establish a HRPP Continuity of Operations Strategy in order to maintain HRPP operations in the event of government closure, whether temporary, prolonged, local, partial (e.g., furlough for some) or national as the result of weather, appropriation lapse, or other national disaster event resulting in a forced reduction in HRPP personnel. The purpose of this strategy is to ensure the safety, rights, and welfare of human subjects participating in OUSD(P&R)-conducted and-supported human subjects research.

11.2. For short term closures for the 59 MDW, the IRB Chair and the AIO will be the official designated essential personnel for IRB and 59 MDW HRPP concerns. If not possible to maintain staffing, OUSD(P&R) HRPP offices may refer customers to an alternate OUSD(P&R) HRPP office. Non-DoD institutions conducting OUSD(P&R)-supported human subject research and research participants in OUSD(P&R)-conducted human subject research must be provided appropriate alternate HRPP contacts.

11.3. If the PI or research monitor is furloughed without an alternate, the research must stop until this regulatory oversight is resumed. Every OUSD(P&R) research study shall be covered by a contingency plan. If protocol deviations are necessary to ensure subject safety and/or welfare, the PI should contact the Office of Clinical Research Support for guidance. The IO/AIOs must assess whether any ongoing research can continue or must stop based on the safety and well-being of research subjects.

11.4. For long term closures affecting the 59 MDW, remaining HRPP staff or, if no HRPP staff remain, the IO/AIO shall report to R2O2 whether staffing is sufficient to oversee the 59 MDW HRPP, and what current HRPP courses of action are being taken. R2O2 will assess the situation and shall determine whether the 59 MDW should continue its proposed courses of action or suspend all research activities.

RANDALL C. LAMBERT, Colonel, USAF, MSC
Administrator

Attachment 1**GLOSSARY OF REFERENCES AND ABBREVIATIONS*****References***

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 44 Federal Register (FR) 23192, 18 April 1979

Title 10 United States Code Section 980, *Limitation on Use of Humans as Experimental Subjects*, 11 October 1985

Title 21 Code of Federal Regulations (CFR) Part 50, *Protection of Human Subjects*, 1 April 2015

21 CFR Part 54, *Financial Disclosure*, 1 April 2015

21 CFR Part 56, *Institutional Review Board*, 1 April 2015

21 CFR Part 312, *Investigational New Drug Application*, 1 April 2015

21 CFR Part 600, *Biological Products*, 1 April 2015

21 CFR Part 812, *Investigational Device Exemptions*, 1 April 2015

32 CFR Part 219, *Protection of Human Subjects*, 1 October 2016 (pre-2018 requirements)

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59 MDW *Human Research Protection Program (HRPP) Operating Instruction (OI), Institutional Review Board*, 15 November 2019

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59 MDW *Human Research Protection Program (HRPP) Steering Committee Charter*, 7 August 2015

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59 MDWI 41-108, *Presentation and Publication of Medical and Technical Papers*, 5 January 2018

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DASD(HRP&O) Operating Instruction, October 3, 2019

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DoDI 3216.02, *Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research*, 8 November 2011

DoDI 3216.02, *Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and –Supported Research*, 15 Apr 2020

DoDI 3216.02_AFI 40-402, *Protection of Human Subjects and Adherence to Ethical Standards in Air Force Supported Research*, 10 September 2014 (Pending 2019 revision).

DoDI 6000.08, *Defense Health Program Research and Clinical Investigation Programs*, 22 January 2014

OASD(HA) Memo, *Component-Level Reliance Agreement for Institutional Review Board Reviews*, 13 November 2019

OUSD(R&E) Memo, *Reduction of Duplicative Research Reviews Involving Human Participants*, 24 October 2019

OUSD(R&E) Memo, *DoD Determination for Cooperative Research Not Using a Single Institutional Review Board*, 16 January 2020

Adopted Forms

59 MDW Form 14, *Financial Conflict of Interest Disclosure*

59 MDW Form 15, *Financial Conflict of Interest Disclosure for 59 MDW Key Personnel*

Abbreviations and Acronyms

AAIO—Alternate Appointed Institutional Official

AF—Air Force

AFMS—Air Force Medical Service

AIO—Appointed Institutional Official

CAC—Common Access Card

CFR—Code of Federal Regulations

CIP—Clinical Investigation Program

CITI—Collaborative Institutional Training Initiative

COI—Conflict of Interest

CONUS—Continental United States

CRA—Clinical Research Administrator

CRADA—Cooperative Research and Development Agreement

DASD(HRP&O)—Deputy Assistant Secretary of Defense for Health, Research, Policy and Oversight

DHHS—Department of Health and Human Services

DoD—Department of Defense

DoDI—Department of Defense Instruction

DTIC—Defense Technology Information Center

FDA—Food and Drug Administration

FWA—Federal-Wide Assurance

GCP—Good Clinical Practice

GHSE—Graduate Health and Science Education

GME—Graduate Medical Education

HIPAA—Health Insurance Portability and Accountability Act

HPA—Human Protections Administrator

HRPO—Human Research Protections Official

HRPP—Human Research Protection Program

HSR—Human Subjects Research

IA—Institutional Approval

IAW—In Accordance With

IAIR—Institutional Agreement for IRB Review

IDE—Investigational Device Exemptions

IIA—Individual Investigator Agreement

IND—Investigational New Drug

IO—Institutional Official

IRB—Institutional Review Board

MDW—Medical Wing

MDWI—Medical Wing Instruction

MTF—Medical Treatment Facility

NIH—National Institutes of Health

OCONUS—Outside CONUS

OHRP—Office of Human Research Protection

OI—Operating Instruction

ORTA—Office of Research and Technology Applications

OUSD(P&R)—Office of the Under Secretary of Defense Personnel and Research

OUSD(R&E)—Office of the Under Secretary of Defense Research and Engineering

PHI—Protected Health Information

PI—Principal Investigator

PII—Personal Identifying Information

R2O2—Research Regulatory Oversight Office

RAM—Radiation Materials

RSC—Radiation Safety Committee

SAC—Scientific Advisory Committee

SAMHS—San Antonio Military Health System

SAMMC—San Antonio Military Medical Center

SES—Scientific Ethics Subcommittee

SOP—Standard Operating Procedure

UPIRSO—Unanticipated Problems Involving Risk to Subjects or Others

USC—United States Code