

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

**59TH MEDICAL WING INSTRUCTION  
41-108**



**26 APRIL 2022**

**Health Services**

**PRESENTATION AND PUBLICATION  
OF MEDICAL AND TECHNICAL  
PAPERS**

**COMPLIANCE WITH THIS PUBLICATION IS MANDATORY**

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Certified by: 59 MDW/STC  
(Mr. Paul Barnicott)

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This Instruction implements Air Force Policy Directive 41-1, *Health Care Programs and Resources*. It establishes policy, assigns responsibilities, and provides procedures for reviewing, clearing, and accounting for duty-related scholarly journal articles, abstracts, technical reports (e.g., case reports, Quality Assurance/Quality Improvement studies, program evaluation studies, conference papers/posters, etc.) and oral presentations prepared by personnel assigned to the 59th Medical Wing (59 MDW) and intended for public release (domestic or foreign). This Instruction encompasses all activities requiring clearance of Department of Defense (DoD) information for public release, as related to the mission of personnel assigned to the 59 MDW. This Instruction applies to all personnel assigned, attached, or on contract to the 59 MDW. This Instruction does not apply to the Air National Guard or Air Force Reserve. Refer recommended changes and questions about this publication to the Office of Primary Responsibility using the AF Form 847, *Recommendation for Change of Publication*. Ensure that all records created as a result of processes prescribed in this publication are maintained IAW Air Force Instruction (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 instruction has been revised throughout and should be reviewed in its entirety.

**1. Overview. It is 59 MDW policy to:**

- 1.1. Fully inform the public of all research, training, and Clinical Investigation Program (CIP) activities relating to the mission of the 59 MDW.
- 1.2. Provide 59 MDW beneficiaries with access to evidence-based diagnosis and treatment and improve the quality of patient care by improving medical knowledge, practices, materiel, pharmaceuticals, and devices.
- 1.3. Support and encourage publication and presentation of scholarly activities of Graduate Health Sciences Education and other allied health programs in the 59 MDW.
- 1.4. Promote high professional standing and foster multidirectional integration of basic research, patient-oriented research, and population-based research, with the long-term aim of improving the health of the public (translational research), collaborations and accreditation of health education and training programs within the 59 MDW.
- 1.5. Ensure all scholarly activities, research, quality assurance (QA)/quality improvement (QI), program evaluations (PE), process improvements (PI) and training projects receive a research determination prior to implementing the project. No retrospective research determinations will be authorized.
- 1.6. Require prior regulatory clearance for all documents, conference papers/posters and oral presentations that involve scholarly activities, research, QA/QI, PE, PI and training projects intended for public release (domestic or foreign).
- 1.7. Account for, review, and clear all information generated by 59 MDW personnel during scholarly, training, and research activities for security and consistency IAW DoDI 5230.09, *Clearance of DoD Information for Public Release* and this Instruction.

**2. Roles and Responsibilities.**

- 2.1. 59 MDW/CC.
  - 2.1.1. Exercises authority, direction, and control over all publications and presentations by 59 MDW personnel as they relate to this Instruction.
  - 2.1.2. Develops and disseminates publications and presentations policy as needed.
  - 2.1.3. Delegates responsibility to conduct, monitor, and oversee the execution of this instruction.
- 2.2. 59 MDW Alternate Institutional Official (AIO) for the Human Subjects Research Protection Program (HRPP).
  - 2.2.1. Ensures reviews of publications and presentations as they pertain to the 59 MDW HRPP, as outlined in 59 MDWI 41-105, *Human Research Protection Program*.
  - 2.2.2. Interprets/follows policies and procedures in accordance with DoDI 3216.02, *Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research*, Section 3.3, Commanders or Directors of DoD Institutions, as they pertain to this Instruction.
  - 2.2.3. Appoints personnel to the 59 MDW Institutional Review Board (IRB) who have been nominated to become 59 MDW Designated IRB Reviewers for the purposes of this

Instruction or to utilize pre-appointed Designated IRB Reviewers for the purposes of this Instruction.

2.3. 59 MDW Institutional Official for the Animal Care and Use Program (ACUP).

2.3.1. Ensures reviews of publications and presentations as they pertain to the 59 MDW ACUP, as outlined in 59 MDWI 40-402, *Animal Care and Use in Clinical Investigations, Training and Research & Development*.

2.3.2. Interprets/follows policies and procedures in accordance with DoDI 3216.01, *Use of Animals in DoD Conducted and Supported Research and Training*.

2.4. 59 MDW Chief Scientist.

2.4.1. Ensures research and development and other CIP/non-CIP funded research activities have a requirement for presentation/publication clearance.

2.4.2. Reports presentation/publication and clearance metrics (as required) to the 59 MDW Board of Directors.

2.5. Director of Clinical Investigations & Research Support (59 MDW/STC).

2.5.1. Ensures CIP-funded activities have a requirement for presentation/publication clearance.

2.5.2. Maintains this instruction and updates it based on DoD, Defense Health Agency, Air Force and 59 MDW policy.

2.5.2.1. Develops, monitors and maintains the process for clearance of 59 MDW publications and presentations on behalf of the 59 MDW.

2.5.2.2. Reports 59 MDW publications and presentations to the Scientific Advisory Committee.

2.5.3. Ensures 59 MDW publications and presentations related to clinical investigation and research activities are submitted into the Defense Technical Information Center (DTIC), based on DoDM 3200.14, Vol. 1, *Principles and Operational Parameters of the DoD Scientific and Technical Information Program (STIP): General Processes*.

2.5.4. Uses DoDI 5230.09 guidance for submissions.

2.6. 59 MDW Commanders and Wing Staff Senior Leaders.

2.6.1. Ensure compliance with this Instruction and 59 MDW HRPP policies regarding research determinations.

2.6.2. Apply controls to ensure clearance of publications/presentations are carried out IAW the framework for the Air Force and local policies.

2.6.3. Ensure all QA/QI and PE/PI activities are cleared for public release and authorized within their command purview.

2.7. Air Force Associate Dean, Graduate Medical Education, and San Antonio Uniformed Services Health Education Consortium (SAUSHEC).

2.7.1. Ensures Air Force program directors, faculty, and trainees within the SAUSHEC are educated in the conduct of scholarly activities (research, training, technical, etc.), in accordance with applicable federal, DoD, and Air Force regulations.

2.8. 59 MDW Personnel.

2.8.1. Ensure that activities intended for publication or public presentation receive a written research determination and/or approval by an appropriate Institutional Review Board, an Institutional Animal Care and Use Committee Chair (for animal research/non-research activities as applicable), or a commander's authorization (as applicable) to publish QA/QI and/or PE/PI data. Determination or approval must accompany the clearance request for publication/presentation release.

2.8.2. More guidance regarding activities that require research/non-research determinations can be found in the 59 MDW IRB Request for Research and/or Human Subjects Determination Form, as well as 32 CFR 219 and DoDI 3216.02.

2.8.3. Ensure that only materials cleared for public release are submitted for official publication/presentation outside of the 59 MDW. This clearance is requested and granted through submission and approval of the 59 MDW Form 3039, *Processing of Professional Medical Research/Technical Publications/Presentations*. For activities conducted at other facilities, this clearance may alternatively be requested and granted through the corresponding public affairs process at those locations. In this situation, although not required for clearance, 59 MDW personnel must still submit a 59 MDW Form 3039 to facilitate 59 MDW documentation and tracking.

2.8.4. Ensure effective organization and technical accuracy; correct grammar, spelling, and sentence structure; appropriateness of discussion and conclusions; compliance with scientific journal or society requirements.

2.8.5. Primary Disclaimer: On all cleared products, add the following statement on the title page of the research/technical manuscript or presentation: ***"The views expressed are those of the [author(s)] [presenter(s)] and do not reflect the official views or policy of the Department of Defense or its Components".*** Note: The disclaimer statement is not required if the material is for internal consumption, i.e., active duty and DoD employees only and does not require Public Affairs review for public release. The disclaimer is required when the material is presented to external audiences when the U.S. Government, USAF, and/or other Service Components run the risk of endorsing or appearing to endorse a specific commercial product or entity.

2.8.6. Disclaimer, Human Subjects Research: Ensure all abstracts, papers, posters, etc., contain the following additional disclaimer statement for non-exempt research involving human subjects:

***"The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DoDI 3216.02.."***

2.8.7. Disclaimer, Animal Research: Ensure all abstracts, papers, posters, etc., contain the following additional disclaimer statement for research involving animals:

***“The experiments reported herein were conducted according to the principles set forth in the National Research Council’s Guide for the Care and Use of Laboratory Animals (8th ed.), and the Animal Welfare Act of 1966, as amended.”***

2.8.8. Disclaimer, Branded Content: When including branded/manufacture-specific content, ensure all abstracts, papers, posters, etc., contain the following additional disclaimer statement:

***“The views of (manufacturer) are not necessarily the official views of, or endorsed by, the U.S. Government, the Department of Defense, or the Department of the Air Force. No Federal endorsement of (manufacturer) is intended.”***

2.8.9. A manuscript/presentation is not considered final for submission until the above criteria are met.

2.8.10. Publication Agreements: 59 MDW authors should submit a completed publisher’s or society’s copyright form indicating that the research/technical work was prepared as part of his/her official duties and, thus, is deemed a “work of the United States Government.” If the publisher’s or a society’s copyright form does not provide options to indicate that the authors are U.S. government employees, the originator should reply using the letter format in [Attachment 2](#) of this instruction.

2.8.11. Intellectual Property: If publication occurs where unsecured IP may be referenced, recommend authors contact the 59 MDW ORTA as soon as possible to submit for patent protection. If non-government co-authors intend to submit or already submitted for patent protect, government authors must notify the 59 MDW ORTA immediately ([usaf.59mdw.mbx.59-mdw-mdw-st-technology-transfer-office@mail.mil](mailto:usaf.59mdw.mbx.59-mdw-mdw-st-technology-transfer-office@mail.mil); 210-292-1019, DSN 554-1019).

2.8.12. Coordinate publisher page charges or color plate charges with the originator’s organization prior to submitting a health sciences research/technical article for publication (not necessary if the originator plans to personally pay for such charges).

2.8.13. Forward all requests for reprints or technical information from persons in former or current communist bloc countries to 59 MDW/PA, who will in turn forward the request to the Air Force Office of Special Investigations or to Air Force Medical Service Public Affairs (AFMS/PA), as appropriate. **Note:** Communist bloc countries are current and former countries which are currently or were once part of the former Soviet Union, to include: Afghanistan, Albania, Angola, Benin, Bulgaria, Cambodia, Congo, Czechoslovakia, East Germany (now German Democratic Republic), Ethiopia, Hungary, Mongolia, Mozambique, Poland, Romania, Somalia, South Yemen, Yugoslavia, China, Cuba, Laos, North Korea and Vietnam.

2.8.14. Provide a copy of the publication to the 59 MDW Clinical Investigations & Research Support (59 MDW/STC) for submission into DTIC or notify the 59 MDW/STC that the publication will be submitted by the investigator into DTIC.

### **3. 59 MDW Form 3039.**

#### **3.1. Benefits of Review:**

3.1.1. The 59 MDW/STC will maintain a current master computer database of all 59 MDW technical publications, posters, and oral presentations cleared for public release.

3.1.2. Division directors, squadron commanders, group commanders, SGN, SGH and the 59 MDW Commander are made aware of medical research/technical publication and oral presentation efforts by assigned personnel through the use of the 59 MDW Form 3039. This awareness aids the preparation of officer and enlisted performance report ratings, endorsements and letters of recommendation.

3.1.3. The 59 MDW can compile its annual medical research scholarly output and meet DoD plans for public access to scientific results from federally funded research. These data facilitate accreditation of residency and fellowship programs, justify funds for continuing health education and, with respect to reports of clinical investigation, defend costs of the medical center's clinical research program.

3.2. The 59 MDW's Office of Public Affairs (59 MDW/PA) will provide a security and policy review of all proposed publications, abstracts, and presentations for publication or dissemination in any public medium (foreign or domestic). This review facilitates coordination with other agencies, as required (e.g., Air Education Training Command, Air Force Surgeon General's Office, etc.).

3.2.1. If an author releases a document before it is officially cleared for public release, the author is in violation of DoDI 5230.09, which states, *“Any official DoD information intended for public release that pertains to military matters, national security issues, or subjects of significant concern to the Department of Defense shall be reviewed for clearance prior to release.”* Official DoD information pertains to and relates to all information that is in the custody and control of the DoD or was acquired by DoD employees as part of their official duties or because of their official status within the DoD.

3.2.2. If the author submits a 59 MDW Form 3039 request, in which the author has already presented their information to the public without official clearance for public release, 59 MDW/PA will conduct their security and policy review and, if no discrepancies have been identified, will respond with *“No security discrepancies were found”* and inform the author *“The publication or presentation is NOT officially cleared for public release.”* This will be reported to the author's supervisor, commander, and the 59 MDW AIO.

3.2.3. The Joint Ethics Regulation (JER) DoD 5500.07-R, *Standards of Conduct*, provides standards of ethical conduct for all DoD personnel and their interactions with other non-DoD entities, organizations, societies, conferences, etc. Part of the 59 MDW Form 3039 review and approval process includes a legal ethics review to address any potential conflicts related to DoD personnel participating in non-DoD sponsored conferences, professional meetings, publication or presentation disclosures to domestic and foreign audiences, DoD personnel accepting non-DoD contributions, awards, honoraria, gifts, etc. The specific circumstances for an author's presentation will determine whether a legal review is necessary. **If an author or an author's supervisor answers “YES” in block 19 of the 59 MDW Form 3039, the author's research or technical documents will be forwarded to the 502 ISG/JAC legal office for an ethics review. If “NO” is answered for block 19, an author's research or technical documents will not be forwarded to the 502 ISG/JAC legal office for an ethics review.** See the 59 MDW Form 3039 instructions for additional guidance on an ethics review.

3.3. Based on DoDM 3200.14, DoD scientific and technical information (STI) must be appropriately managed to enable scientific knowledge and technological innovations to be

fully accessible to authorized recipients, while applying appropriate safeguards to assure that the information is protected, as necessary. The preparation and distribution of STI in the form of medical research journal articles/abstracts, conference papers, technical reports, etc., and other means external to DoD will not be in lieu of providing those same documents to DTIC, appropriate DoD Information Analysis Centers and the 59 MDW technical library.

3.4. The originator will complete page 2 of the 59 MDW Form 3039, sign the form, and have their unit commander, Program Director, or immediate supervisor sign the form. The originator will attach the publication/presentation (including illustrations) and research/non-research determination memo or commander's authorization to the 59 MDW Form 3039 request and submit the documents to 59 MDW/STC for processing [[usaf.jbsa.59-mdw.mbx.wing-crd-publications-and-presentations@mail.mil](mailto:usaf.jbsa.59-mdw.mbx.wing-crd-publications-and-presentations@mail.mil)]. **Note:** *For each new release of medical research/technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval. If a previously approved presentation is presented again without substantive changes, the presenter may simply submit a copy of the original presentation, plus another 59 MDW Form 3039, to document the most recent presentation request.*

3.5. The originator will retain the original manuscript or abstract for eventual submission to the publisher or society. Proposed medical research/technical manuscripts for publication must be submitted through 59 MDW/STC prior to any commitment to civilian publishers. The originator should **not** submit an abstract or medical research/technical manuscript to publishers or societies for consideration until they receive telephone or written notification from the 59 MDW/STC that the work was approved for public release.

3.6. For medical research presentations not based on a manuscript or article (e.g., lectures from slides, table-top clinics, etc.), the originator should submit a general description of the subject matter to be presented. Proposed medical research/technical presentations must be submitted through the 59 MDW/STC prior to any commitment to civilian societies. The originator should **not** submit a medical research/technical presentation to societies for consideration until they receive verbal or written notification from the 59 MDW/STC that the work was approved for public release.

3.7. Upon receipt of the proposed medical research/technical manuscript, abstract, or presentation, the 59 MDW/STC will assign a file number and enter the processing information into a master spreadsheet for database tracking purposes.

3.8. The 59 MDW/STC will review all submissions for the criteria cited in Sections 3 and 4 of this instruction. The reviewer may detect errors or suggest changes which would enhance the chances of acceptance by the publisher or society. The reviewer will notify the originator of any recommended or required change(s).

3.9. The 59 MDW/STC will forward all submissions and illustrations to 59 MDW/PA for an official security and policy review for medical research/technical manuscript/presentation clearance. If the submissions require an ethics review, or the submission involves animal research, 59 MDW/STC will forward to the 502 ISG/JAC legal office and then forward to 59 MDW/PA.

3.10. The 59 MDW/PA will forward manuscripts/presentations to the AFMS/PA and/or to the Secretary of the Air Force for Public Affairs Security Review (SAF/PAS), if additional review/clearance is deemed necessary.

3.11. The 59 MDW/PA will work with the 59 MDW/STC to revise any items not consistent or compliant with current Air Force, DoD, or federal security policies.

3.12. The 59 MDW/PA will return the cleared material to the 59 MDW/STC for further processing.

3.13. Following 59 MDW/PA actions, the 59 MDW/STC will promptly notify the originator as to the approval or disapproval of the publication, abstract, or presentation material. If approval is granted, the originator may then submit the manuscript, abstract, or presentation to the journal, publisher, or society for public release.

3.14. The 59 MDW/STC will retain all records pertaining to the 59 MDW Form 3039 clearance process.

**4. Time-Requirements for Presentation and Publication Clearance.** The originator should submit their completed 59 MDW Form 3039 and all supporting documents to the 59 MDW/STC Publications and Presentations Office for processing, ***no later than 30 days before final clearance is required to publish/present their materials.*** The 59 MDW/PA office has ten (10) working days to complete the entire review and clearance process. However, if additional higher-level review is required, more time must be allowed. Information for foreign release must be processed through disclosure channels, which may take 60-90 days to complete. An individual who does not obtain proper review and clearance of their research/technical publication or presentation in time will only receive a security review from 59 MDW/PA, but ***not*** clearance for public release.

## **5. Publication Funding.**

5.1. Clinical Investigations Program funding is available for health science residents and Fellows to publish if SAUSHEC or program funds are not available.

5.1.1. In the event that a residency program director is informed that the residency program cannot support a resident's cleared publication, the resident should contact the 59 MDW/STC with a request for 59 MDW/STC funding support at: [usaf.jbsa.59-mdw.mbx.wing-crd-protocol@mail.mil](mailto:usaf.jbsa.59-mdw.mbx.wing-crd-protocol@mail.mil).

5.1.2. The request for 59 MDW/STC funding will require verification that the residency program is unable to support the resident publication.

5.1.2.1. The request for publication funding must be submitted prior to publication, and will include the Form 3039, cleared publication and invoice from the publisher.

5.1.2.2. Reprint costs will not be provided/funded by the 59 MDW/STC.

5.1.2.3. Funds are available on a first-come basis until all available funds for publications are obligated for the current fiscal year.

5.2. Funding requests for non-resident 59 MDW personnel whose commander is unable to fund publication costs should be directed to the Office of the Chief Scientist at: [usaf.jbsa.59-mdw.mbx.chief-scientist-hrpp@mail.mil](mailto:usaf.jbsa.59-mdw.mbx.chief-scientist-hrpp@mail.mil); website is: <https://www.59mdw.af.mil/Units/Chief-Scientist-ST/Human-Research-Protection-Program/>

5.2.1. The Office of the Chief Scientist will provide information regarding non-CIP funding [e.g., AFMSA/SG5 R&D; Tri-Service Nursing Research Program; Defense



Medical Research & Development Program; Congressionally Directed Medical Research Program, etc.].

5.2.2. Activities that cannot be supported by the Office of the Chief Scientist may be eligible for 59 MDW funding for publication.

JEANNINE M. RYDER, Brig Gen, USAF, NC  
Commander

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

- 10 U.S.C. 139, *Director of Operational Test and Evaluation*, 31 December 2020
- 10 U.S.C. 1074f, *Medical Tracking System for Members Deployed Overseas*, 1 January 2021
- 10 U.S.C. 1102, *Confidentiality of Medical Quality Assurance Records: Qualified Immunity for Participants*, 7 January 2011
- 32 CFR 219, *Protection of Human Subjects*, 19 January 2018
- 59 MDWI 40-402, *Animal Care and Use in Clinical Investigations, Training and Research & Development*, 4 April 2021
- 59 MDWI 41-105, *Human Research Protection Program*, 7 October 2020
- AFI 35-101, *Public Affairs*, 20 November 2020
- AFI 44-119, *Medical Quality Operations*, 16 August 2011
- AFPD 41-1, *Health Care Programs and Resources*, 3 October 2018
- Animal Welfare Act of 1966, as amended
- DHA ORP Guidance (GD 20-103), *Research Determinations for Process Improvement, Quality Improvement, and Evidence-Based Practice Projects*, 2 March 2020
- DHA ORP PI, *Protecting Human Subjects in Research*, 7 September 2020
- DHA PI 3200.02, *Clinical Investigation Program (CIP) in Military Medical Treatment Facilities (MTFs)*, 24 September 2019
- DoDD 5141.02, *Director of Operational Test and Evaluation (DOT&E)*, 2 February 2009
- DoDI 3216.01, *Use of Animals in DoD Conducted and Supported Research and Training*, 20 March 2019
- DoDI 3216.02, *Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research*, 15 April 2020
- DoDI 5230.09, *Clearance of DoD Information for Public Release*, 25 January 2019
- DoDI 6025.13, *Medical Quality Assurance (MQA) and Clinical Quality Management in the Military Health System (MHS)*, 17 February 2011, Incorporating Change 2, 1 April 2020
- DoDI 6200.02, *Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Program*, 27 February 2008
- DoDM 3200.14, Vol. 1, *Principles and Operational Parameters of the DoD Scientific and Technical Information Program (STIP): General Processes*, 14 March 2014, Incorporating Change 2, 15 October 2018
- DoDM 8910.01, Vol. 1, *DoD Information Collections Manual: Procedures for DoD Internal Information Collections*, 30 June 2014, Incorporating Change 2, 19 April 2017

HQ USAF/CVA Letter, *USAF Visit and Disclosure Policy Concerning Foreign Nationals or Their Representatives*, 14 November 1983

Joint Ethics Regulation (JER) DoD 5500.07-R, *Standards of Conduct*, 17 November 2011

### ***Prescribed Form***

59 MDW Form 3039, *Processing of Professional Medical Research/Technical Publications/Presentations*

### ***Adopted Form***

AF Form 847, *Recommendation for Change of Publication*

### ***Acronyms and Abbreviations***

**AFMAN**—Air Force Manual

**AIO**—Alternate Institutional Official

**CIP**—Clinical Investigation Program

**DoD**—Department of Defense

**DTIC**—Defense Technical Information Center

**IAW**—In Accordance With

**IRB**—Institutional Review Board

**MDW**—Medical Wing

**PE**—Program Evaluation

**PI**—Process Improvement

**QA**—Quality Assurance

**QI**—Quality Improvement

**SAUSHEC**—San Antonio Uniformed Services Health Education Consortium

**STI**—Scientific and Technical Information

### ***Terms***

**Case Study**—Use of medical information collected from a clinical activity rather than a research activity and presented on an individual or a small group of patients [e.g., three (3) patients]. Case reports are generally done by retrospective review of the medical record and highlight a unique treatment, case or outcome. The examination of the case is usually not systematic and there is usually no data analysis or testing of a hypothesis. Investigators must ensure that the HIPAA privacy rules are followed with respect to using or accessing PHI (a HIPAA authorization or waiver may be required).

**Class Projects**—Student assignments involving collection of data from human subjects when the data is used solely for the purpose of teaching course content (e.g., to teach proficiency in performing certain tasks or using specific tools or methods) and not intended to be used to develop or contribute to generalizable knowledge.

**Compliance Assessments**—Activities performed solely for assessing compliance of individuals and organizations with requirements applicable to military, civilian, or contractor personnel or to organizational units, including such activities as occupational drug testing, occupational health and safety reviews, network monitoring and monitoring for compliance with requirements for protection of classified information.

**Customer Satisfaction Survey**—Assesses program users to obtain feedback for use by program managers. Similar to program evaluation, the purpose of these surveys is to improve a specific service or program or develop new services or programs under the control of the individual/organization obtaining the information and not to conduct research.

**Domestic Release**—Includes societies composed primarily of Department of Defense (DoD) personnel but whose proceedings may be distributed to the public or may be reported by the public news media (e.g., The Society of Air Force Physicians, The Society of American Federal Medical Laboratory Scientists, The Air Force Society of Clinical Surgeons).

**Foreign Release**—Includes any symposium or conference which is open to foreign representation.

**Health Surveillance**—This refers to activities carried out solely for purposes of diagnosis, treatment, or prevention of injury and disease in Service members and other mission essential personnel under *force health protection programs* of the Department of Defense, including *health surveillance* pursuant to 10 U.S.C. 1074f (medical tracking system for members deployed overseas) and the use of medical products consistent with DoDI 6200.02. Health surveillance is an ongoing part of the medical care and public health care functions closely integrated with timely dissemination of these data to those responsible for preventing and controlling disease or injury (may include emergent or urgently identified or suspected imminent health threats to the population to document the existence and magnitude). Health Surveillance entails monitoring diseases, medical costs, public health clinical parameters, trending analyses, etc. This is NOT considered research.

**Patient Treatment**—Authorized health and medical activities as part of the reasonable practice of medicine or other health professions undertaken for the sole purpose of patient treatment.

**Program Evaluation**—Assesses the success of established programs in achieving mission objectives and program performance when the assessments are for the use of DoD program managers, for example, a survey to determine if program beneficiaries are aware of the availability of program services or benefits. Program evaluations are generally sponsored and approved through the local Commander or higher HQs. Release of study results outside the chain of command requires the local Commander's approval or authorization from higher HQs. It is allowable to publish how a program evaluation was conducted, but the information gathered is NOT for generalizable knowledge. **Note:** Non-research evaluation is generally designed to assess or improve the program or service rather than to generate knowledge about a disease or condition.

**Publicly Available Data**—Research involving publicly available information (e.g., census data, labor statistics) does not constitute human research.

**OT&E Activities**—Operational, Test and Evaluation (OT&E) activities performed solely for an OT&E project, as defined in 10 USC 139(a)(2)(A) and DoDD 5141.2.

**Quality Assurance**—This refers to activities performed for the sole purpose of medical quality assurance, as covered by 10 U.S.C. 1102 and DoDD 6025.13. Quality assurance refers to activities

particular to an institution's QA program, such as those activities protected from disclosure by the 59 MDW Quality Assurance Program, the Department of Veterans Affairs as part of its confidential medical quality assurance program or other equivalent programs (see applicable policy or instruction). The purpose of a Quality Assurance (QA) study is to assure known quality based on a given standard. A QA study should present NO RISK to participants. Such projects are usually for internal auditing purposes only and are generally not considered research. QA activities can be research, if they are also intended to contribute to generalizable knowledge. **Note:** QA evaluations are considered confidential and are generally sponsored and approved through the local commander or senior leadership. Release of QA study results outside of the chain of command requires approval from the local commander or senior leadership who authorized the QA evaluation.

**Quality Improvement**—Quality improvement is systematic, data-guided activities designed to bring about immediate, positive changes in the delivery of health care in particular settings. QI involves deliberate actions to improve care, guided by data reflecting the effects of local care (e.g., types of practical problem solving; an evidence-based management style; the application of science of how to bring about system change; review of aggregate data at the patient/provider/unit/organizational level to identify a clinical or management change that can be expected to improve care). Improve implies change. QI is generally not considered research – however, QI activities can be research, if they are also intended to contribute to generalizable knowledge.

**Research**—Any activity that is a systematic investigation, including Research Development, Test & Evaluation, designed to develop or contribute to generalizable knowledge as defined in 32 CFR 219.102(d). (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).

**Scholarly Activity**—In accordance with the Accreditation Council for Graduate Medical Education (ACGME) guidance for educational programs, scholarly activity is defined as: Peer-reviewed funding; Publication of original research or review articles in peer-reviewed journals, or chapters in textbooks; Publication or presentation of case reports or clinical series at local, regional, or national professional and scientific society meetings; Participation in national committees or educational organizations.

**Technical Report**—A document written by a researcher detailing the results of a project and submitted to the sponsor of that project. The Department of Energy, National Aeronautics and Space Administration, and Department of Defense are top sponsors. A number of U.S. Government sponsors now make technical reports available full image via the internet. Although technical reports are very heterogeneous, they tend to possess the following characteristics: Technical reports may be published before the corresponding journal literature; Content may be more detailed than the corresponding journal literature, although there may be less background information since the sponsor already knows it; Technical reports are usually not peer reviewed

unless the report is separately published as journal literature; Classified and export controlled reports have restricted access; and obscure acronyms and codes are frequently used.

## Attachment 2

**SAMPLE LETTER OF TRANSMITTAL GRANTING PERMISSION TO PRINT  
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Title: (Research/Technical Manuscript Title)

Author(s): Maj John Doe, Capt Joe Smith

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59 MDW/ (Group/Squadron)

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(Author's Signature) (mm/dd/yyyy)

JOHN DOE, Maj, USAF, MC                      Date